STATEMENT OF CONSIDERATION
Relating to 401 KAR 5:320
(Amended After Comments)

I. The public hearing on 401 KAR 5:320, scheduled for April 25, 2013, at 5 p.m. at 300 Fair Oaks Lane, Conference Room 301D, Frankfort, Kentucky, was held; several members of the public did attend this public hearing including Mr. Brian Wilt (Marathon Petroleum Company), Mr. Michael Campbell (Marathon Petroleum Company), Ms. Rhonda Baker (Beckmar Lab), Ms. Kimberly Fallon (Beckmar Lab), Ms. Margaret Center (Beckmar Lab), Ms. Robin Strader (KLA), Mr. Jack Bates (Bates and Skidmore), Ms. Linda Swearingen, Ms. Samantha Horn, Ms. Christina Thomas, Mr. David Lester, Mr. Bill Scalf, Mr. Fanta Bayo, Mr. Don Swearingen, Mr. Eric Chance (Appalachian Voices), Ms. Ellen Fouser, Ms. Rita Wright (Fouser Environmental Services), Ms. Annette Dupont-Ewing (KMUA), Mr. Mike Baumgardner (McCoy Labs), Mr. Doug Wolfe (McCoy Labs), Mr. Ronnie McKee, and Mr. Ken McCarter. Mr. Eric Chance (Appalachian Voices), Mr. Michael Campbell (Marathon Petroleum Company), Ms. Annette Dupont-Ewing (KMUA), and Ms. Robin Strader (KLA) provided verbal comments. Written comments were also received regarding this administrative regulation. Representing the Energy and Environment Cabinet were Sandy Gruzesky, Division of Water (DOW) Director, and Jon Trout, DOW Branch Manager.

II. The following people submitted written comments:

Name and Title	Agency/Organization/Entity/Other
Thomas Crockett, Biologist	Straight Creek Coal Mining Inc.
Gene Solomon, QA Officer	Anatek Labs, Inc.
Barry Sparks, EHS Specialist	Owensboro Specialty Polymers
Charlene Baker, Sr. Env. Eng.	ISP Chemicals, LLC
William Wells, Chief Engineer	The Wells Group, LLC
Gil Dichter, Manager	IDEXX Labs
Rita Wright	Fouser Environmental Services
Joey Tackett	TEE Engineering Co., Inc.
Gary Yakub, Chemist	Environmental Standards, Inc.
Eric Hickman, Environmental Analyst	Owensboro Municipal Utilities
Tracy Hunt, Environmental Specialist	International Paper
Cathy Vessels, Water Quality Analyst	Owensboro Municipal Utilities
Laurent Rawlings, Vice President	Home Builder's Association of Kentucky
Gregory Busch, QA Officer	Heritage Environmental Services, LLC
Ronnie McKee, Operator	Cynthiana Wastewater Treatment Plant

Jim Sumner, Director	Environmental Testing Solutions, Inc.
John Myers, Director	Tennessee Valley Authority (TVA)
Tyler Campbell, Legislative Liaison	Kentucky League of Cities (KLC)
Rusty Cress, Legal Counsel	Kentucky Association of Manufacturers (KAM)
Robin Strader, Operator	Leitchfield Wastewater Treatment Plant and Kentucky Laboratory Analysts Committee (KLA)
Suzanne Tallichet, Chairperson	Kentuckians For The Commonwealth (KFTC)
Tim Joice, Director	Kentucky Waterways Alliance (KWA)
Bill Bissett, President	Kentucky Coal Association (KCA)
Fanto Bayo, Chemist	City of Frankfort
Chad Harpole, Vice President	Kentucky Chamber of Commerce
Eric Chance, Water Quality Specialist	Appalachian Voices
Judy Morgan, Vice President	ESC Lab Sciences
Alan Wood, Director	American Electric Power Service Corporation (AEP)
Annette DuPont-Ewing	Kentucky Municipal Utilities Association (KMUA)
Michael Campbell	Marathon

III. The following people from the promulgating administrative body responded to the written comments:

Name and Title

Jon Trout, Resource Planning and Program Support Branch Manager
Tom Gabbard, Compliance and Technical Assistance Branch Manager
Frank Hall, Laboratory Certification Coordinator
Peter Goodmann, DOW Assistant Director
Danielle Crosman, Internal Policy Analyst III

IV. Summary of Comments and Responses

(1) Subject Matter: Financial and regulatory burden on cities

(a) Commenter: Tyler Campbell, KLC

Comment: KLC believes the Division has done an admirable job in seeking input from entities that may be impacted by the proposed legislation. KLC believes that allowing substantial input prior to promulgation avoids substantial disagreement further in the process. Nevertheless, KLC is tremendously concerned with the likely unnecessary burdens, both financial and regulatory, the proposed regulation will have on Kentucky's cities. KLC understands that the Energy and Environment Cabinet ("Cabinet") has statutory authority to promulgate the regulation. However, the Cabinet is not mandated by the statute to do so.

(b) Response: The Cabinet appreciates KLC's participation in the development of this regulation. Based upon investigations the Cabinet has conducted of laboratories in Kentucky conducting wastewater monitoring and testing services, the Cabinet has determined that quality control and quality assurance procedures at some wastewater laboratories are inadequate, in part, due to a lack of

clear regulatory standards and certification programs for wastewater laboratories. Due to these findings, the Cabinet proposed and the Kentucky General Assembly adopted legislation during the 2011 regular session to create standards and a certification program for laboratories conducting analysis of wastewater for KPDES program purposes. The legislation was codified at KRS 224.10-670, which became effective June 8, 2011. This proposed administrative regulation, as amended, establishes the wastewater laboratory certification program, standards for the certification of wastewater laboratories, and fees for certification and evaluation of wastewater laboratories. The intent of the wastewater laboratory certification program is to ensure that the integrity of KPDES compliance data can be ascertained. The Cabinet has, as much as possible, taken every effort to minimize the cost and regulatory burden of the wastewater laboratory certification program.

(2) Subject Matter: Quality Assurance Plans and Standard Operating Procedures for Field Analyses

(a) Commenters: Alan Wood, AEP; Fanto Bayo, City of Frankfort

Comment: The Kentucky Wastewater Laboratory Certification Program Application requires wastewater laboratories only performing field analyses to develop and submit a quality assurance plan and standard operating procedures, as well as proficiency test results of the primary analyst/technician. Based on the criteria set forth in the March 2013 Wastewater Laboratory Certification Manual, development of a quality assurance plan (QAP) and standard operating procedures (SOP) will require significant effort by facility personnel. The regulation should make clear the deadlines for the QAP and the SOP to be developed. The implementation of a quality assurance plan and applicable procedures would require additional man-hours as personnel would be required to follow strict protocols for sampling, analysis, quality control, and documentation. Completing periodic reports, annual reviews and evaluations, training, etc. would also add to the existing workload for personnel. There is insufficient time from now until July to develop these documents.

This issue is critical because staff at the Big Sandy Plant is limited due to economic conditions. Other organizations in Kentucky are also feeling this effect. While important to ensure analytical procedures and data for field analyses are accurate, we feel applying the same criteria for quality assurance plans and standard operating procedures as required for analytical laboratories is excessive. AEP therefore recommends the criteria for quality assurance plans and standard operating procedures for laboratories

only performing field analyses be limited. This will help ensure plans and procedures are consistent with the level of detail necessary for field analyses and limit the amount of personnel hours required to obtain/maintain certification.

(b) Response: The Cabinet has, as much as possible, taken every effort to minimize the cost and regulatory burden of the program. Other than requiring certification of wastewater laboratories, the proposed regulation, as amended, does not impose any additional requirements beyond the requirements of 40 CFR Part 136, which already apply to Clean Water Act §402 (NPDES) compliance data. However, the Cabinet recognizes that field analyses should be viewed and treated differently than the more complex analyses conducted in a laboratory. In that regard, the Cabinet has proposed in Section 2 of this administrative regulation, as amended, to establish the effective date of this administrative regulation as January 1, 2015 for "Field Only Wastewater Laboratories." In addition, the Cabinet has proposed in Section 14 this administrative regulation, as amended, to simplify the certification process for "Field Analysis" by developing SOP and QAP templates to assist facilities in obtaining certification. The Cabinet will provide public notice of these templates and an opportunity for public comment on the proposed templates.

A KPDES permitted facility that is providing field analyses for its own facility is exempt from certification fees in accordance with this regulation. It is also important to note that process-control analyses are not subject to this regulation.

(3) Subject Matter: Discharge Monitoring Report-Quality Assurance (DMR-QA) Program participation as an alternative for a Proficiency Test (PT) Study

(a) Commenter: Thomas Crockett, Straight Creek Coal Mining Inc.
Comment: Can you expound on the Discharge Monitoring Report-Quality Assurance (DMR-QA) Program participation as an alternative for a PT Study?

(b) Response: A DMR-QA is a PT Study that includes additional restrictions imposed by the U.S. Environmental Protection Agency (EPA), such as being required in the first six months of the year. Therefore, if a facility performs a successful DMR-QA as required by a KPDES permit, that DMR-QA would be accepted as meeting the PT Study requirement of this regulation for that method-analyte pairing.

Currently, not every PT Study would meet the EPA's requirement for a DMR-QA. However, after adoption of this proposed regulation and approval of Kentucky's WLCP by the EPA, the

Cabinet intends to request approval from the EPA to implement the DMR-QA program in Kentucky. If approved, the EPA's DMR-QA program would be subsumed by the WLCP, and a KPDES permit holder would no longer be required to demonstrate compliance with the EPA's DMR-QA program.

(4) Subject Matter: Reciprocity

(a) Commenter: Gene Solomon, Anatek Labs, Inc.

Comment: In the past we have maintained drinking water certification in Kentucky, and that has been through a reciprocal acceptance of our Idaho and Florida NELAP certification. I haven't found anything yet in the information you sent that references reciprocity – is the current plan for the Division of Water to only directly accredit out-of-state labs?

(b) Response: The proposed administrative regulation, as amended, includes a provision for "equivalency of certification." Section 1 (3) of this proposed administrative regulation, as amended, defines "equivalency of certification" and Section 8 (6), as proposed, provides a 20 percent reduction of fees for a wastewater laboratory seeking equivalency of certification.

(5) Subject Matter: Exemptions

(a) Commenters: Barry Sparks, Owensboro Specialty Polymers; Charlene Baker, ISP Chemicals, LLC

Comment: Are there going to be any exemptions if you are already doing another program or just field analysis? It looks like if you are already doing the DMR-QA study that this would be enough certification. Can a certified wastewater operator perform field analyses at a permitted facility without laboratory certification? This was not mentioned in the Wastewater Laboratory Certification Manual.

(b) Response: KRS 224.10-670 requires all data submitted for compliance with a KPDES permit be analyzed by a wastewater laboratory certified by the Cabinet pursuant to this proposed administrative regulation, as amended. The proposed administrative regulation, as amended, does not provide an exemption for a facility participating in another program, such as the EPA's DMR-QA program. The Cabinet intends to request approval from EPA to implement the DMR-QA program in Kentucky. If approved, the EPA's DMR-QA program would be subsumed by the WLCP, and a KPDES permit holder would no longer be required to demonstrate compliance with the EPA's DMR-QA program.

A KPDES permitted facility conducting compliance sample analyses for only "field" parameters, will be required to obtain certification for "Field Analysis Only" in accordance with Section

1(4) of this proposed administrative regulation, as amended. The permitted facility must seek certification, not the certified operator. The Cabinet is developing SOP and QAP templates to assist facilities in obtaining "Field Analysis" certification. A KPDES permitted facility that is providing field analyses for its own facility is exempt from certification fees in accordance with this regulation.

(6) Subject Matter: Chlorine residual test method

(a) Commenter: Barry Sparks, Owensboro Specialty Polymers

Comment: What method is established in 40 C.F.R. 136 for chlorine residual, ((c) A method, including instrumentation, established in 40 C.F.R. 136 or the applicable permit) for Lab certification?

(b) Response: Section 3 (1) of this proposed administrative regulation, as amended requires that environmental data from analyses and laboratory tests submitted to the cabinet for activities subject to 33 U.S.C. 1342, shall be performed: by a certified wastewater laboratory; and in compliance with an analytical method in 40 C.F.R. Part 136 or as established in the applicable permit. Below is a copy of part of the table in 40 CFR 136.3 that identifies approved chlorine residual test methods.

Parameter	Methodology [58]	EPA [52]	Standard methods	ASTM	USGS/AOAC/Other
17. Chlorine-Total residual, mg/L	Amperometric direct		4500-Cl D-2000	D1253-08	
	Amperometric direct (low level)		4500-Cl E-2000		
	Iodometric direct		4500-Cl B-2000		
	Back titration ether end-point[15]		4500-Cl C-2000		
	DPD-FAS		4500-Cl F-2000		
	Spectrophotometric, DPD		4500-Cl G-2000		
	Electrode				See footnote.[16]
17A. Chlorine-Free Available, mg/L	Amperometric direct		4500-Cl D-2000	D1253-08	
	Amperometric direct (low level)		4500-Cl E-2000		
	DPD-FAS		4500-Cl F-2000		
	Spectrophotometric, DPD		4500-Cl G-2000		

[15] The back titration method will be used to resolve controversy.

[16] Orion Research Instruction Manual, Residual Chlorine Electrode Model 97-70. 1977. Orion Research Incorporated. The calibration graph for the Orion residual chlorine method must be derived using a reagent blank and three standard solutions, containing 0.2, 1.0, and 5.0 mL 0.00281 N potassium iodate/100 mL solution, respectively.

(7) Subject Matter: Wastewater laboratory certification for in-house testing and flow

(a) Commenters: Charlene Baker, ISP Chemicals, LLC; Chad Harpole, Kentucky Chamber of Commerce

Comment: Flow is included in the list of field analyses and it is a parameter on our KPDES permit that we are required to report on the DMR. Will we then have to certify our wastewater lab (which primarily does in-house testing)? If not, would we be required to perform field analysis quality control as stated in 4.3?
In Section II, General Laboratory Requirements, 4.2, Field Analysis Activities Performed by the Permitted Facility, it states "an employee of a permitted facility may perform the following field analyses: . . ." The program scope should exclude KPDES measurements not associated with an approved analytical method. As proposed, the analysis category "field analysis" is defined to include flow measurement. Flow measurement involves an assessment (measurement or estimate) of an entire water stream rather than evaluation of a sample; it is not a laboratory analysis and is not included among the analytical methods promulgated at 40 CFR Part 136. KPDES permits may likewise require monitoring for other parameters not mentioned within the proposed rule, such as precipitation, that similarly have nothing to do with laboratory methods. As proposed, a facility that measures flow but contracts with outside analytical labs for all other KPDES parameters would still be classified as a wastewater laboratory subject to the requirements of this certification program, including compliance with the Wastewater Laboratory Certification Manual. Parameters not associated with an analytical method approved under 40 CFR Part 136 should be excluded from the scope of this program.

(b) Response: The Cabinet agrees, and has determined that flow is more appropriately categorized as a calculation than a measurement or analysis. Therefore, flow has been removed from the definition of "field analysis" in Section 1 of the proposed administrative regulation, as amended.

The proposed administrative regulation <u>does not</u> require that the person collecting compliance samples in accordance with the KPDES permit be associated with a certified wastewater laboratory. Sample collection requirements are part of the KPDES permit. Sample collection must be conducted in compliance with the applicable requirements of the methods identified in 40 CFR Part 136. The notable exception to this being field analysis. If the person collecting KPDES compliance samples is also conducting field analyses as defined in the proposed administrative regulation, that person must be associated with a wastewater laboratory certified for Field Analysis.

(8) Subject Matter: Sampling procedures and training

(a) Commenter: Charlene Baker, ISP Chemicals, LLC

Comment: In Section III, Critical Elements for Chemistry, 5.5, Sample Collector (if provided by the certified laboratory), it states "the sample collector shall have the proper training in sampling procedures and have suitable sampling instructions for each type of sample to be collected." Our contract laboratory field technician collects all grab samples however our operators collect composite, stormwater outfall, and whole effluent toxicity samples. Will our operators be able to continue to collect these samples as a permitted facility without laboratory certification? If yes, would they be required to follow sampling procedures as outlined in the manual?

(b) Response: The operators will be able to continue to collect samples at the facility without seeking certification. The proposed administrative regulation does not require that the person collecting compliance samples in accordance with the KPDES permit be associated with a certified wastewater laboratory. Sample collection requirements are part of the KPDES permit. Sample collection must be conducted in compliance with the applicable requirements of the methods identified in 40 CFR Part 136. The notable exception to this being field analysis. If the person collecting KPDES compliance samples is also conducting field analyses as defined in the proposed administrative regulation, that person must be associated with a wastewater laboratory certified for Field Analysis.

(9) Subject Matter: SOP and other requirements

(a) Commenter: Charlene Baker, ISP Chemicals, LLC

Comment: In Section III, Critical Elements for Chemistry, 5.7, Sample Compositing, it states "use of an automated field composite sampler shall be performed according to the manufacturer's specifications and meet the requirements of the specific program." We are required to collect 24-hr composite samples for BOD, TSS, and metals. If we are not a certified laboratory, will we have to maintain a standard operating procedure (SOP) and other requirements for the composite sampler?

(b) Response: Sample collection requirements are part of the KPDES permit. Sample collection must be conducted in compliance with the applicable requirements of the methods identified in 40 CFR Part 136. Guidance for using the composite sampler can be found in Handbook for Sampling and Sample Preservation of Water and Wastewater, EP-600/4-82-029 (September 1982). The notable exception to this being field analysis. If the person collecting KPDES compliance samples is also conducting field analyses as

defined in the proposed administrative regulation, that person must be associated with a wastewater laboratory certified for Field Analysis.

(10) Subject Matter: Receiving water requirement in KPDES permit

(a) Commenter: Charlene Baker, ISP Chemicals, LLC

Comment: In Section V, Critical Elements for Whole Effluent Toxicity, 1.3, Receiving Water Sampling, it states in 1.3.1 that "A representative grab sample shall be collected from the receiving water as specified in the KPDES permit." We discharge to the Tennessee River. Would that be our receiving water? Would we be required to collect Tennessee River water samples when we collect samples for WET test? We do not have access to our outfall (it is on the property of a neighboring facility). Also, we now have a draft KPDES permit and after an initial review, receiving water is not specified nor is it required to be collected.

(b) Response: The Cabinet has determined that the Wastewater Laboratory Certification Manual should not provide guidance for or include requirements not in 40 CFR 136 in regards to WET testing. Therefore, the Cabinet is revising Chapter V of the Manual to revise the introduction (1.1) and remove Sections 1.2 and 1.3.

Regarding the specifics of the KPDES permit requirements, those questions are outside of the scope of this administrative regulation and should be directed to the Division of Water's Surface Water Permits Branch.

(11) Subject Matter: Certification timeframes, fee schedule

(a) Commenter: William Wells, The Wells Group, LLC

Comment: I believe that your proposed certification period of 2 years is too short. Five years would be more appropriate. Furthermore, the certification fees listed in your fee schedule are excessive. I understand that is how the EPA operates. It wants shorter certification and permit periods along with excessive fees in order to generate more revenue for your Department. I disagree with this *modus operandi*. I do not believe you should see your Department as profit center. You should attempt to fulfill your mission of protecting the environment at the least cost to society and the economy.

(b) Response: The cabinet agrees that costs should be minimized as much as possible and has taken every effort to minimize cost and regulatory burden of the program. The fee structure is designed to cover only the cost for the Cabinet to operate the program. The Cabinet believes that the frequency of certification is adequate to ensure integrity of compliance data.

(12) Subject Matter: Testing in wastewater

(a) Commenter: Rita Wright, Fouser Environmental Services

Comment: In the general requirements Section II of the certification manual, regarding 3.9.2.2 on page II-5, should this be confirmation/ verification of presumptive total coliform positive samples or should it be E. coli? I thought they were only testing for E. coli in wastewater?

(b) Response: A laboratory shall be certified for the analytical methods employed at the laboratory. The Manual Section II 3.9.2.2 is inclusive of all coliform methods. The water quality standards retain both the E. coli and fecal coliform standards, as both standards still exist within active permits. The method of analysis required is specified in the KPDES permit. Therefore, the Manual needs to address testing for both fecal coliforms and *E. coli*. The Cabinet has not made changes based on this comment.

(13) Subject Matter: Duplication in manual

(a) Commenter: Rita Wright, Fouser Environmental Services

Comment: In Section II General Requirements part 8.0 on Equipment and Supplies the pH meter and balance are mentioned but not the conductivity meter; however, in Section IV 3.0 on page IV-3 Equipment and Supplies the conductivity meter is mentioned but not the pH meter and balance. I know these pieces of equipment may be used for both micro and chemistry but couldn't understand why some items were duplicated in part II and IV and not others...e.g. plasticware, temperature monitoring devices, etc? Seems like the pH meter and balance definitely need to be covered in Section IV since it is so critical for media checks/prep. Also may need to be there when you set up your checklist for each section - is it possible that some labs will be certified for general chemistry but not micro?

(b) Response: The Cabinet believes that the requirements are more appropriately included in a general section. Therefore, the Cabinet has not made changes based on this comment. One of the goals in writing the Manual was to reduce redundancy. While some items may be important to a particular type of laboratory (for example, a pH meter to a microbiology laboratory), that item may also be relevant for other types of laboratories. Where the Manual does repeat an item, such as glassware or thermometers, some additional requirements or details were appropriately added as applicable to a specific section, such as sterile tips, glassware and plasticware non-toxic to microorganisms, etc. in the microbiology section.

(14) Subject Matter: Applicability of the General Section; Refrigeration

(a) Commenter: Rita Wright, Fouser Environmental Services

Comment: On the section on the refrigerator it says they must be maintained at less than or equal to 6 degrees; it also says this on the section on maintaining temperature of field samples. I understand that SM says to maintain samples in transport at less than or equal to 6 but does this also mean the refrigerator since the micro samples are suppose to be between 1-5 degrees? Should I put this in my QC manual even for the micro equipment QC since the refrigerator isn't mentioned in the micro section IV?

(b) Response: The General Section (Chapter II of the Manual) applies to all laboratories. If a requirement is in the General Section of the Manual and that requirement is not modified in a subsequent laboratory-specific section, that requirement of the General Section shall be met regardless of the type of laboratory. If there is a subsequent requirement that is specific to a particular type of laboratory, that laboratory-specific requirement shall be met. The Cabinet has not made changes based on this comment.

(15) Subject Matter: Redundancy

(a) Commenter: Rita Wright, Fouser Environmental Services

Comment: I am having a very hard time following the equipment sections (general, micro and chemistry) in the manual. I really think there shouldn't have been a general section for equipment and the equipment put in each section, micro or chemistry. I think the wastewater operators (analyst) will have a hard time following the manual also. Is there anyway that this can be changed at this point? It seems so redundant to put a general and then a section on equipment and supplies when they will have to follow a checklist for each section.

(b) Response: The Cabinet believes that by including universal requirements in the General Section, Chapter II of the Manual, wastewater laboratory personnel can more easily identify the requirements in Chapters III, IV, and V of the Manual that apply to only specific types of laboratories. The General Section applies to all laboratories. If a requirement is in the General Section and that requirement is not modified in a subsequent laboratory-specific section, that requirement of the General Section shall be met regardless of the type of laboratory. If there is a subsequent requirement that is specific to a particular type of laboratory, that laboratory-specific requirement shall be met. The Cabinet has not made changes based on this comment.

(16) Subject Matter: Field meter calibration requirements

(a) Commenter: Joey Tackett, TEE Engineering Co., Inc.

Comment: I need some clarification on the field meter calibration requirements in the WW Lab Cert Manual. The manual states that meters shall be calibrated using a primary standard each day of

use. It also says the quarterly quality control sample (QCS) requirement may be satisfied by using a primary standard for daily calibration verification. I'm having difficulty sourcing a product described as a "primary standard" for pH. In the past we have purchased NIST-traceable standards. Will that still be acceptable? If not, could you point me in the direction of a source for the required standards?

(b) Response: Chapter III, Section 7.4 of the Manual states that a "primary standard" is a National Institute of Standards and Technology (NIST)-traceable standard. A "secondary standard," such as a "gel-type standard," is not a NIST-traceable standard. If a primary standard is used for daily calibration a quarterly QCS is not required. If a secondary standard is used for daily calibration, a quarterly QCS is required using a primary standard. The Cabinet has not made changes based on this comment.

(17) Subject Matter: Implementation

(a) Commenter: Gary Yakub, Environmental Standards, Inc.

Comment: Could you provide an update on the projected implementation of the Kentucky Wastewater Laboratory Certification program? Will Kentucky be using a national accreditation standard, such as NELAC, or a state-developed accreditation standard for certification requirements? When does Kentucky project that the laboratory on-site audits will begin?

(b) Response: The proposed regulation recognizes other national accreditation standards, such as NELAC, and provides that laboratories certified under other accreditations can seek certification in accordance with this regulation via the "equivalency of certification" provision in Section 1(3) "Equivalency of certification," which means certification of a wastewater laboratory by an entity, other than the cabinet, whose requirements for certification are determined by the cabinet to meet the requirements of this administrative regulation.

The effective date of the proposed administrative regulation, as amended, is January 1, 2014, for general wastewater laboratories. The effective date of the proposed administrative regulation, as amended, is January 1, 2015 for Field Only Wastewater Laboratories.

A laboratory certified pursuant to this administrative regulation is subject to audit upon issuance of the interim certification. A KPDES permitted facility certified for "Field-Only Wastewater Laboratory" will be subject only to KPDES inspections, unless such inspections identify significant problems with the field analyses.

(18) Subject Matter: Field test for pH

(a) Commenter: Eric Hickman, Owensboro Municipal Utilities

Comment: We have a lab that performs field analysis for our KPDES permit. It seems we would be exempt from any fees. However, one question arose on how we field tested our pH. We do not test it in the field, we collect a sample and bring it back to the lab (which is on site) to run it on our bench top pH meter. Would this be considered field testing? We measure our total residual chlorine in the same manner, collect in field but bring back to lab to analyze. Would this still be considered field analysis as well?

(b) Response: A KPDES-permitted facility that is conducting only field analyses for its own facility is exempt from certification fees in accordance with this regulation. All of the parameters listed in the definition of "field analysis" in Section 1(4) of the proposed administrative regulation, as amended, are considered a part of "field analysis" regardless of where the actual analysis takes place. This includes both pH and residual chlorine analytes.

(19) Subject Matter: Certification terms

(a) Commenter: Eric Hickman, Owensboro Municipal Utilities

Comment: Reading the regulation it states the first term of certification is 7/1/13 – 12/31/14 and the recertification must be submitted every November 15th on even number years. If I read this correctly, OMU will need to send its initial certification package to the Cabinet in the 7/1/13-12/31/14 timeframe, then we would need to recertify the same year or wait until 11/15/16?

(b) Response: The effective date of the proposed administrative regulation, as amended is January 1, 2014, for general wastewater laboratories. The effective date of the proposed administrative regulation, as amended is January 1, 2015, for Field-Only Wastewater Laboratories. Data submitted for purposes of compliance with a KPDES permit must be analyzed by a wastewater laboratory in compliance with this regulation within one year of the (applicable) effective date of this administrative regulation (i.e. either January 1, 2015 or January 1, 2016 – for Field-Only Wastewater Laboratories). The certification of the wastewater laboratory is for a two-year period. Assuming that OMU applied for and received initial certification in 2014, OMU would not be required to apply for recertification until 2016.

(20) Subject Matter: Volume check for sample containers

(a) Commenter: Rita Wright, Fouser Environmental Services

Comment: Why are you checking MF funnels (3.7.2) for measuring the sample to ensure 100 mL is processed for an MF method and not requiring that sample containers (volume check) is performed

under 3.11 for use with Colilert method; even if it is in dilution format? 4.2.1 should be 3.11.5.

(b) Response: The Cabinet believes that a volume check for sample containers is not necessary for a wastewater laboratory program because the entire volume is not used in the required analysis. The Cabinet has not made changes based on this comment.

(21) Subject Matter: Fecal coliforms testing

(a) Commenter: Rita Wright, Fouser Environmental Services

Comment: 3.7.3 -References mEndo Broth or Endo LES media when these are not approved for wastewater in Table IA of the MUR of CFR 136. The only MF method approved for E. coli is mColiBlue24. The statement should be….(e.g. blue colonies on mColiBlue24 media). This of course is assuming that Kentucky is requiring E. coli only and not fecals for wastewater.

1.1.2 – E. coli method or fecal coliform, depending on which group of organisms the facility chooses to test and again in 1.1.5 fecal is referenced….It was my understanding that KY would only be testing for E. coli in wastewater after all new permits were issued?

(b) Response: The water quality standards retain both the E. coli and fecal coliform standards, as both standards still exist within active permits. The method of analysis required is specified in the KPDES permit. Therefore, the Manual needs to address testing for both fecal coliforms and *E. coli*. The Cabinet has not made changes based on this comment.

(22) Subject Matter: Autoclave temperature

(a) Commenter: Rita Wright, Fouser Environmental Services

Comment: Under 3.3.2 (of the Manual) – Autoclave it is stated that the autoclave shall maintain a sterilization temperature of 119-124ºC which is what is written in the KY DOW Version of the 5th Ed. of the Laboratory Certification Manual for Drinking Water Analysis, not the USEPA version which states 121º. The USEPA Region IV auditor recommends the upper level from 121-124ºC range; at any rate it should be written as one of the three ways.

In 3.7.4 – Membrane Filters it states that filters and pads be autoclaved for 10 minutes at 121ºC. Also, in 4.1.1, autoclaving times again reference 121ºC. How can you give a specific temperature of 121ºC if they are allowed to be within a range on their autoclave sterilization temperature?

(b) Response: The Cabinet agrees. Chapter IV section 3.3.2 of the Manual has been changed to identify that 121°C is the temperature set point for the autoclave but compliance is determined by the range 119°C to

124°C. 121°C is the target sterilization temperature. In the autoclave section, a range is given to allow approximately 2% in either direction from the target of 121°C. Thus, the requirement is to set the autoclave at 121°C, but compliance is achieved if the actual temperature is within the given range. The Cabinet has not made changes based on this comment.

(23) Subject Matter: Use of glass plates

(a) Commenter: Rita Wright, Fouser Environmental Services

Comment: 3.8.1 (of the Manual) should only say pre-sterilized plastic plates used. Glass plates are only in large sizes and would not meet the requirements for 3.8.4. They would have no need for large petri plates unless they prepare MacConkey (which they should purchase commercially) for sterility check of their QC organisms. They may also use 10 glass plates for the Inhibitory Residue Test.

(b) Response: While the Cabinet recognizes that a pre-sterilized plastic plate may be a practical choice, a laboratory may use a glass plate if it meets the requirements of Chapter III Section 3.8 of the Manual.

(24) Subject Matter: Refrigerator temperature restrictions

(a) Commenter: Rita Wright, Fouser Environmental Services

Comment: 8.4.2 – Refrigerator – Second sentence…exceed these limits. Here again this should state…exceed or fall below 1-5ºC for a refrigerator. This is not referring to a sample received from collector as I stated in a previous comment about 8.4.1 which should also be 1-5ºC for a refrigerator and not ≤6.0ºC as required for field samples being received by the lab.

(b) Response: The Cabinet agrees that the language in the Manual should be clarified; the Cabinet has changed the wording in Chapter 2 Section 8.4.2 to "falls outside the limits established in Chapter II Section 8.4.1."

(25) Subject Matter: Use of sterile dilution water

(a) Commenter: Rita Wright, Fouser Environmental Services

Comment: 4.4 – Dilution/Rinse Water (add Sterile Water to Title): This section covers dilution water used for MF method but also needs a number for sterile water used for Colilert (or emphasize in 4.4.3). General Methodology 1.1.4. Sterile Water is mentioned for dilutions but does not specify that it must be used for samples being processed using Colilert method.

(b) Response: The Cabinet believes that by including universal requirements in the General Section, Chapter II of the Manual, wastewater laboratory personnel could more easily identify the requirements in Chapters III, IV, and V of the Manual that apply to only specific types of laboratories. The General Section applies to all laboratories. If a requirement is in the General Section and that

requirement is not modified in a subsequent laboratory-specific section, that requirement of the General Section shall be met regardless of the type of laboratory. If there is a subsequent requirement that is specific to a particular type of laboratory, that laboratory-specific requirement shall be met. The Cabinet has not made changes based on this comment.

(26) Subject Matter: Presence/absence methods for E. coli
(a) Commenter: Rita Wright, Fouser Environmental Services
Comment: 1.1.6.4.2 – Laboratories performing presence/absence methods (no enumeration methods) may inoculate 100 mL of serial dilution. It is my understanding that for wastewater that all methods for E. coli must be enumerative; therefore, this statement is not needed.
(b) Response: The Cabinet agrees. The sentence referring to presence/absence methods has been removed from Chapter IV Section 1.1.6.4.2 in the Manual.

(27) Subject Matter: Combining sections on sample containers
(a) Commenter: Rita Wright, Fouser Environmental Services
Comment: Why are sample containers discussed in 3.11 and 4.2? Why can these two (2) not be put together under 3.11?
(b) Response: Chapter IV Sections 3.11 and 4.2 of the Manual address different aspects and do not lend themselves to being combined. Chapter IV Section 3 pertains to equipment and supplies and Chapter IV Section 4 pertains to general laboratory practices. Therefore, the Cabinet has not made changes based on this comment.

(28) Subject Matter: Sterilizing sample containers
(a) Commenter: Rita Wright, Fouser Environmental Services
Comment: 4.2.2 (of the Manual) – Sample Containers – it begins "a blank tray/bottle (with sterile water and media) shall be processed at least once daily to ensure the sterility of the trays, bottles, media, and sealer. Bottles are QC with broth when a new lot is purchased and doesn't need to be QC daily; Media has already been covered in 1.1.6 and need not be covered in this section; QC of each new lot or batch of prepared media; Media controls may be processed each day samples are processed. Quanti-Trays should be QC when a new lot is received using 100 mL of TSB. This should have a section of its own…should specify Quanti-Trays and not just trays. Sealer should be checked monthly using 100 mL of water and a food color (dye of some sort); this should have a section of its own. Could change Quanti-Trays and Sealer to make them Section 4.2 instead of under Sample Containers. Put all sample container information under 3.11.
(b) Response: The purpose of the Section 4.2.2 was to provide a daily sterility check to ensure no contamination was introduced at the lab during

analysis. It is common (e.g. chemistry methods) to require daily processing of a blank or one blank per batch of twenty samples. This gives the analyst an opportunity to demonstrate that contamination was not introduced through technique nor the supplies/equipment used to run samples that day, and thus provides greater validity for the associated results. The Cabinet agrees that the sealer check should be included in the Manual and will add a new Section 3.13 to Chapter IV of the Manual. QC for media is covered in Chapter IV Section 1.1.6 of the manual. Media is referenced again in Chapter IV Section 4.2.2 of the manual for blank purposes. The Cabinet does not believe that this is a repeat requirement.

(29) Subject Matter: Correct use of conjunction
(a) Commenter: Rita Wright, Fouser Environmental Services
Comment: 3.2.1 -Should be "or" instead of "and".
(b) Response: The Cabinet agrees that the conjunction should be "or" instead of "and" and has made this change to Chapter IV Section 3.2.1 of the Manual.

(30) Subject Matter: Performing Heterotrophic Plate Counts
(a) Commenter: Rita Wright, Fouser Environmental Services
Comment: Why is not reference made in Section IV about methods for performing Heterotrophic Plate Counts (HPC) on Reagent Grade Water QC? How can the method be audited without some reference in the manual to either the Pour Plate Method or SimPlate Method?
(b) Response: The Cabinet agrees that the SIMPlate Method should be an acceptable option and has added this to Table IV-3 in Chapter IV of the Manual. A laboratory is required to be certified only for methods used for compliance samples. A laboratory is not required to be certified for the HPC method used to check the reagent grade water. Likewise, the Pour Plate Method is used to test the reagent grade water (see footnotes of Table IV-3) and does not require that the wastewater laboratory be certified for this method.

(31) Subject Matter: Quality Control and documentation for all requirements
(a) Commenter: Rita Wright, Fouser Environmental Services
Comment: It is my understanding that when auditing a laboratory that all "shall" statements must be QC and have documentation that these items are being performed. I do not understand how this is possible on several of the items in the manual that are shalls (e.g., etched or broken pipettes)….Will the deviation be given based on the auditor's observations and not documentation?

(b) Response: Documentation of compliance with the regulation is the responsibility of the certified laboratory. The auditor will use both observations and written documentation, as appropriate, in determining compliance.

(32) Subject Matter: Including specific methods in manual

(a) Commenter: Rita Wright, Fouser Environmental Services; Eric Chance, Appalachian Voices

Comment: The manual primarily addresses basic measurement techniques, while only touching on the more sophisticated, instrument-based methods such as spectrophotometry, gas chromatography, infrared spectroscopy and gas chromatography/mass spectrometry. Many automated instruments are commonly in use and these should require extensive training, maintenance and calibration procedure that are not addressed in the manual. For example, why are specific methods (mColiBlue24 and Colilert) for E. coli not discussed in Section IV since they are the only two methods approved for E. coli under CFR 136? It seems like the lab would have more direction in developing SOPs and QC Manual if information for micro was more specific. I realize that for the chemistry side there are several methods approved for each analyte and this would not be an effective approach, however, it would make the micro side easier if the specific methods were discussed (section under MF and Enzyme Substrate).

(b) Response: As a result of suggestions from stakeholders, and in the interest of brevity the Cabinet agreed not to include in the Manual the details of stand-alone methods in 40 CFR 136. Otherwise, the procedures can be easily accessed when needed.

(33) Subject Matter: Becoming a certified laboratory

(a) Commenter: Tracy Hunt, International Paper

Comment: We do onsite wastewater testing which results are submitted on DMR's. I know there was a bill passed for all wastewater labs to become certified. As I understand it, we are grandfathered in for year 2013, but need to be audited in 2013 to become certified for 2014. If I am correct, how do I proceed forward with the audit process to become a certified lab?

(b) Response: The effective date of the proposed administrative regulation, as amended, is January 1, 2014, for general wastewater laboratories. The effective date of the proposed administrative regulation, as amended, is January 1, 2015 for Field-Only Wastewater Laboratories. Data submitted for purposes of compliance with a KPDES permit must be analyzed by a wastewater laboratory in compliance with this regulation within one year of the (applicable) effective date of this administrative regulation (i.e. either January 1, 2015 or January 1, 2016 – for Field-Only Wastewater

Laboratories.) The application for certification, which is incorporated by reference in the Section 15 of the proposed regulation, identifies the information that is required to be submitted to the Cabinet along with the program fee. The certification of the wastewater laboratory is for a two-year period. The cabinet will audit a wastewater laboratory after interim certification is granted for that lab.

(34) Subject Matter: Proficiency Test (PT) Studies for informational sampling
(a) Commenter: Cathy Vessels, Owensboro Municipal Utilities
Comment: Are we still required to do PT's on conductivity and turbidity? We do not perform either in the field and are not required for our permit.
(b) Response: If a facility is not required by its KPDES permit to submit conductivity or turbidity data, then the facility is not required to become certified or to conduct PT studies for those tests.

(35) Subject Matter: Support for proposed regulation
(a) Commenter: Gil Dichter, IDEXX Labs
Comment: Overall, it is a well balanced document to ensure quality in the lab and I fully support this.
(b) Response: The Cabinet acknowledges the comment.

(36) Subject Matter: Media Fluorescence – Microbiology
(a) Commenter: Gil Dichter, IDEXX Labs
Comment: My input is for several items under Chapter IV of the Manual. Critical Elements for Microbiology. IV-3 1.1.6.8 I do not see this procedure in the USEPA Lab Certification manual. The statement, if the medium exhibits faint fluorescence is very subjective and is not the best way for interpretation. We as the manufacturer check each lot per our specifications. My suggestion, if this stays in, is to compare it against the "comparator", any fluorescence observed must be less than that of the comparator.
(b) Response: Chapter IV Section 1.1.6.8 of the Manual identifies a requirement that is included in the 5th edition of the EPA Manual for the Certification of Laboratories Analyzing Drinking Water (Chapter V; 5.3.1.2.3). The basis for this provision is based on whether a medium already produces a faint amount of fluorescence is combined with a sample that also produces a faint amount of fluorescence, the cumulative effect may result in a sample test with a positive outcome for fluorescence, even though the sample itself may not have generated a result of fluorescence greater than the standard to which it is being compared. Therefore, the Cabinet has not made changes to the Manual as a result of this comment.

(37) Subject Matter: UV Lamp Quality Control

(a) Commenter: Gil Dichter, IDEXX Labs

Comment: IV-8 3.1.2.2 Test the longwave UV lamp. Should length be added to wavelength? This is not indicated in the USEPA Lab Certification manual. If this stays in, I would like to suggest an alternative as follows: Yearly replace the UV lamp. This should be part of the SOP, the date received and replaced shall be recorded. Sending out the lamp or buying this equipment is quite expensive. If the lab has someone in to check the short wavelength UV then they can also check the long wavelength. Some facilities may not have a germicidal unit and it can be quite expensive

(b) Response: The term "longwave UV lamp" is used in Chapter IV Section 3.12 of the Manual as an equivalent to "long wavelength UV lamp". Depending upon the bulbs used and the amount of use, the bulbs may need to be replaced more or less frequently than on a yearly basis. Therefore the Cabinet believes that a requirement to check UV lamps quarterly is more appropriate than the suggested requirement to replace the UV lamps yearly. In the situation of a wastewater laboratory without a UV meter, an alternate option is available for evaluating the lamp by using a positive control. Therefore, the Cabinet has not made any changes to the Manual.

(38) Subject Matter: Sterility Control Checks

(a) Commenter: Gil Dichter, IDEXX Labs

Comment: IV-9 4.2.2 I am surprised to see this in the document to check a tray or bottle at least once/day. Is this really necessary? Tray and bottles are sterile and this should not be necessary. There can be scenarios that someone can contaminate a bottle or tray and not realize it. I would rather see that the trays and bottles are properly stored and or use correctly in the lab.

(b) Response: The Cabinet believes that the inclusion in Chapter IV Section 4.2.2 of the Manual for processing this blank will improve the integrity of wastewater laboratory analysis results by demonstrating that the test was conducted without introducing contamination, and is therefore reasonable. Therefore, the Cabinet has not made any changes to the Manual.

(39) Subject Matter: Field vs. Non-field Analysis

(a) Commenters: Laurent Rawlings, Home Builder's Association of Kentucky; Chad Harpole, Kentucky Chamber of Commerce

Comment: Overall, HBAK has applauded the idea of KDOW establishing a Wastewater Lab Certification Program. However, we must call attention to the lack of differentiation within the Wastewater Lab Certification Program between routine field testing and the more involved non-field testing. While the complexities of non-field/commercial certification process are necessary, those same complexities should not be required of common field certification.

In our estimation, to regulate these as commensurate is a misunderstanding of the fundamental call for laboratory certification, firstly, and will necessarily drive up costs to existing KPDES permit holders.

Program requirements should be minimal for KPDES field tests. The proposed regulation creates the analysis category "field analysis" (Section 1, paragraph 4), which appears intended to capture simple tests and measurements performed outside a laboratory setting using field kits or meters. As proposed, a facility performing no KPDES measurement other than pH or temperature would be fully subject to the certification program, including the obligations for application, compliance with the Wastewater Laboratory Certification Manual (including QAP development), Cabinet audits, Cabinet certification, and annual participation in a proficiency test study (such as DMR-QA, which currently applies only to major and select minor NPDES facilities). Even without fees, this is surely an unnecessary compliance burden for small facilities, holders of minor KPDES permits, and KPDES facilities that perform only field tests. Facilities performing no KPDES analyses or tests other than field analyses should be exempt from program requirements beyond registration.

(b) Response: The Cabinet appreciates HBAK's and the Chamber's support of and participation in the development of the Wastewater Lab Certification Program. Other than requiring certification of wastewater laboratories, the proposed regulation, as amended, does not impose any additional requirements beyond the requirements of 40 CFR Part 136, which already apply to Clean Water Act §402 (NPDES) compliance data. However, the Cabinet agrees that field analyses should be viewed and treated differently than the more complex analyses conducted in a laboratory. In that regard, the Cabinet has proposed to simplify the certification process for "Field Only" wastewater laboratories. The cabinet is developing SOP and QAP templates to assist facilities in obtaining "Field Analysis Only" certification. A KPDES permitted facility that is providing field analyses for its own facility is exempt from certification fees in accordance with Section 8 (9) of this regulation. The Cabinet intends to request approval from EPA to implement the DMR-QA program in Kentucky. If approved, the EPA's DMR-QA program would be subsumed by the WLCP, and a KPDES permit holder would no longer be required to demonstrate compliance with the EPA's DMR-QA program.

(40) Subject Matter: Request for Additional Public Comment

(a) Commenter: Laurent Rawlings, Home Builder's Association of Kentucky

Comment: The Cabinet requests compliance by referencing a publication that is incomplete. Section 2 indicates that, as of 1 July 2014, all environmental data from analyses or tests subject to 33 U.S.C 1342 (the NPDES program, implemented in Kentucky through KPDES permits) shall be performed in compliance with the provisions of the Commonwealth of Kentucky Wastewater Laboratory Certification Manual. It must be noted that, as of this writing, section VI of said manual, "Critical Elements of In-stream Monitoring," is incomplete, and is listed as "reserved." It is due to this tentative state that we recommend that prior to any changes and/or revisions made in the Commonwealth of Kentucky Wastewater Laboratory Certification Manual, such changes and/or revisions be public noticed and adhere to the full administrative regulatory process, with a 60-day comment period in place.

(b) Response: The Cabinet has removed the reserved Chapter VI from the Manual. Any revisions made to the Manual after the proposed administrative regulation goes into are required to comply with the KRS 13A administrative regulatory process, including public notice, public comment, and opportunity for public hearing.

(41) Subject Matter: Field analysis

(a) Commenter: Gregory Busch, Heritage Environmental Services, LLC

Comment: The regulation would not allow consultants or engineering firms to perform sampling. The only way they could become accredited is if they register as a wastewater lab, purchase, analyze and report PT samples, write the required QA Plans and Standard Operating Procedures etc. These are all the things that labs do. This would effectively require a consultant or engineering firm to effectively become a 'lab' for field parameters if they wanted to perform this service. Our laboratory would have the documentation and studies required, but it would be very costly (and therefore undesirable to our Kentucky clients) to send our staff to Kentucky to sample field parameters. It is not clear there would be a way for a laboratory to "subcontract' this except to another 'certified lab'. The majority of field sampling in environmental work is performed by consultants, not laboratories.

(b) Response: The Cabinet appreciates the concern and seeks to clarify the requirements regarding sample collection herein. The Cabinet does not intend to eliminate the practice of field sample collection by consultants and other contracted entities. The proposed administrative regulation does not require that the person collecting compliance samples in accordance with the KPDES permit be associated with a certified wastewater laboratory. Sample collection requirements are part of the KPDES permit. Sample collection must be conducted in compliance with the applicable requirements of the methods identified in 40 CFR 136.

The notable exception to this being field analysis. If the person collecting KPDES compliance samples is also conducting field analyses as defined in Section 1 (4) the proposed administrative regulation, as amended, that person must be associated with a wastewater laboratory certified for Field Analysis.

(42) Subject Matter: Class A volumetric calibration

(a) Commenters: Gregory Busch, Heritage Environmental Services, LLC; John Myers, TVA

Comment: There is no justification or precedent for the requirement that laboratories calibrate their Class A volumetric glassware annually. Most laboratories have hundreds of small pipettes and numerous other glassware that would be very difficult to label, clean and maintain labeling. Class A glassware should never need calibration unless it is subject to extreme heat or dropped, which in that case must be replaced. This would be a high burden, difficult to administer and audit; it would not add value to testing. Paragraph 8.5.4 Annual "calibration" wording should be changed to "check" instead since nothing can be adjusted. Modern commercial grade laboratory ware is manufactured to excellent tolerances and annual checks are simply not necessary. Daily checks for dirt and chips are a requirement.

(b) Response: The Cabinet agrees and has removed the phrase "shall be calibrated annually and adjusted or replaced if the precision or accuracy is greater than 2.5%" from Chapter II Section 8.5.4 of the Manual. Section 8.5.4 will be replaced with "All pipets shall meet the requirements of their applicable use." For purposes of consistency, the Cabinet has removed the reference to Class A in Chapter II Section 8.5.3 of the Manual, leaving the requirement that glass and plastic pipets delivering volumes of 10 ml or less shall be accurate to within a precision of 2.5%.

(43) Subject Matter: Concern about certification and PT costs

(a) Commenter: Ronnie McKee, Cynthiana WWTP Operator

Comment: I feel that either way, it's going to be a financial burden on small municipalities. If they decide to get the lab certified, there is the expense of the permit and for each classification of testing. If they have the testing done by a contract lab, there is the cost of the testing and sample pick up and it usually takes at least 2 weeks to get the results back. You cannot run a plant on 2 week old results, so they are still going to have to run the test in house, even though they cannot report them, for process control. Then you have the extra cost of running the test twice. In operator certification, we are taught that if you run a test you report it, now it's going to be just the opposite, unless the lab is certified. Will there be any

consideration for plants that have been doing the DMR-QA for years and passing all the time?

(b) Response: The cabinet appreciates the comment and has, as much as possible, taken every effort to minimize the cost of the program. Other than requiring certification of wastewater laboratories, the proposed regulation, as amended, does not impose any additional requirements beyond the requirements of 40 CFR Part 136, which already apply to Clean Water Act §402 (NPDES) compliance data. Process control analyses, such as those referred to in the comment above, are not subject to this regulation. There is no exemption from the requirements of this regulation for a facility participating in another program, such as the EPA's DMR-QA program. The Cabinet intends to request approval from EPA to implement the DMR-QA program in Kentucky. If approved, the EPA's DMR-QA program would be subsumed by the WLCP, and a KPDES permit holder would no longer be required to demonstrate compliance with the EPA's DMR-QA program.

(44) Subject Matter: Definitions

(a) Commenter: Jim Sumner, Environmental Testing Solutions, Inc.

Comment: (3) Equivalency of Certification means certification of a wastewater laboratory by an entity, other than the cabinet, whose requirements for certification are determined by the cabinet to meet the requirements of this administrative regulation.

Request the cabinet specify which entities meet the requirements of this administrative regulation. For example, our laboratory is certified by the North Carolina Division of Water Quality to perform whole effluent toxicity tests. Under this certification, the NC DWQ audits our laboratory annually. Does this certification meet the cabinet's requirements?

(b) Response: The proposed regulation recognizes other national accreditation standards, such as NELAC, and provides that laboratories certified under other accreditations can seek certification in accordance with this regulation via the "equivalency of certification" provision in Section 1(3) "Equivalency of certification," which means certification of a wastewater laboratory by an entity, other than the cabinet, whose requirements for certification are determined by the cabinet to meet the requirements of this administrative regulation.

(45) Subject Matter: Annual Certification Fees

(a) Commenter: Jim Sumner, Environmental Testing Solutions, Inc.

Comment:

Table 1	Annual Fee
Whole effluent toxicity	$1,000

Request fee for whole effluent toxicity is reduced to less than or equal to the inorganic general chemistry fee ($500). For a

commercial laboratory, certification for inorganic general chemistry (or any of the other categories) would enable that laboratory to perform testing for a larger group of clients. This would result in the potential of a much higher revenue base than laboratories which perform only whole effluent toxicity tests. The fees should reflect this revenue base.

(b) Response: The fees set forth in Section 8 of the proposed administrative regulation, as amended, are based on the Cabinet's cost to administer the certification program. The fees are not based on the presumptive revenue base of a laboratory. The cabinet has taken every effort to minimize costs for the program; the fee structure is designed to cover only the cost for the Cabinet to operate the program, and to minimize the regulatory burden of the program.

(46) Subject Matter: Information required for equivalency of certification

(a) Commenter: Jim Sumner, Environmental Testing Solutions, Inc.

Comment: (6) A wastewater laboratory seeking or obtaining equivalency of certification shall receive a twenty (20) percent reduction of certification fee. Provide clarification on the requirements and/or certification that meets "equivalency of certification".

(b) Response: The proposed administrative regulation, as amended, recognizes other national accreditation standards and makes provisions for laboratories certified under other accreditations to seek certification in accordance with this regulation via the "equivalency of certification" provision in Section 1(3) "Equivalency of certification," which means certification of a wastewater laboratory by an entity, other than the cabinet, whose requirements for certification are determined by the cabinet to meet the requirements of this administrative regulation.

Section 5 of the application titled Kentucky Wastewater Laboratory Certification Program Application for Kentucky Laboratory Certification provides an option for initial and renewal equivalency of certification, directing the applicant to complete Section 9 or 12, respectively. Sections 9 and 12 of the application provide the list of what information is required to be submitted for equivalency of certification. The additional information required for initial equivalency certification is: (a) Scope of work, which includes a copy of the current certificate and a list of analytes currently certified along with the reference method, instrument, laboratory minimum reporting limit, method detection limit, and units for each analyte, and (b) The most recent final audit report issued by the certifying authority, including any corrective action plan, and any other information required by the Cabinet to demonstrate compliance with all of the requirements for initial certification.

(47) Subject Matter: Unannounced audits
(a)Commenter: Jim Sumner, Environmental Testing Solutions, Inc.
Comment: (1) A certified wastewater laboratory shall allow a cabinet auditor to conduct, and shall participate in, an on-site audit during normal business hours without prior notification. Request that "without prior notification" be removed from the statute. Smaller laboratories, with limited staffing, would not always be able to accommodate an audit without prior notification.
(b) Response: The Cabinet understands the concern raised in the comment. The Cabinet has amended the proposed administrative regulation to delete the language: "without prior notification" in Section 10 (1). The Cabinet reserves the right to conduct an audit without prior notification.

(48) Subject Matter: Incorporation by reference
(a) Commenter: Jim Sumner, Environmental Testing Solutions, Inc.
Comment: Request "or subsequent revision" be included with each reference provided.
(b) Response: The Cabinet appreciates the comment. KRS 13A.2251 requires that the edition date of a document incorporated by reference be included in the administrative regulation.

(49) Subject Matter: Field Analysis Definition
(a) Commenter: John Myers, TVA
Comment: Page 2, lines 13 through 20 "Field Analysis" - The definition of field analysis is incomplete in that it does not exclude measurement of the same parameters within a laboratory facility. TVA suggests that this definition should be restricted to the measurements taken in a field setting such as a settling pond, pipeline, discharge point stream, and the like.
(b) Response: Section 1(4) of the proposed administrative regulation, as amended, defines "field analysis" All of the parameters listed in the definition of "field analysis" are considered as part of this group, regardless of where the actual measurement takes place.

(50) Subject Matter: Requirements for notification to Cabinet
(a) Commenter: John Myers, TVA
Comment: Page 9, lines 14 through 17 "Section 9(2)(c)" - TVA suggests the addition of "material" in the requirement to notify the cabinet within 30 days of a change in equipment, personnel, etc., since an equipment change-out with a new item of the same manufacturer/model, or a change in non-analytical personnel (such as custodians, clerical staff, etc.) may not warrant notification.
(b) Response: Section11 (2)(c) of the proposed administrative regulation, as amended, requires a notification to the Cabinet of any change in

personnel, equipment, analytical method, or laboratory location in its application, but does not include "material." The Cabinet did not change the regulation in response to this comment.

(51) Subject Matter: Logbooks and bench sheets
(a) Commenter: John Myers, TVA
Comment: Chapter II (of the Manual). General Laboratory Requirements, Section 3.0 Quality Assurance Plan (QAP). This section does not address procedures for handling logbooks and bench sheets. TVA suggests adding a section setting policy regarding the issue and other control of logbooks and control of bench sheets.
(b) Response: Documentation of compliance with the regulation is the responsibility of the certified laboratory, including the procedures for managing and maintaining logbooks and bench sheets. The certified laboratory is responsible to ensure that the integrity of the data can be ascertained. Chapter II Section 3.5.1 of the Manual requires that laboratory notebooks shall be recorded in indelible ink or kept electronically, entries dated and signed. The Cabinet has not made changes to the Manual based on this comment.

(52) Subject Matter: Criteria for flagging data
(a) Commenter: John Myers, TVA
Comment: Paragraph 3.5.5 - on occasion, such as in emergency response, a sample would need to be run even if temperatures were out of specification. TVA suggests editing this paragraph to read "Criteria for flagging or rejection of samples that do not meet ....."
(b) Response: The Cabinet agrees that on occasion it is necessary to analyze a sample despite that one or more parameters (e.g. temperature) are out of specification, and agrees that flagging the resultant data is an appropriate approach to managing this information. Therefore, the Cabinet has changed the wording in Chapter II Section 3.5.5 of the Manual to include the suggested language.

(53) Subject Matter: Clarification of sample checks
(a) Commenter: John Myers, TVA
Comment: Paragraph 3.5.6 - for clarity, TVA suggests changing this paragraph to read "Describe how samples are checked and how checks are documented when samples arrive. Checks should include verification of proper containers, temperature, other preservation, and custody seals."
(b) Response: The Cabinet agrees with this comment and has changed the language in Chapter II Section 3.5.6 of the Manual to: "Checks shall include verification of proper containers, temperature, other preservation, and custody seals when applicable."

(54) Subject Matter: Calibration definition

(a) Commenter: John Myers, TVA
Comment: Section 4.0 Field Sampling and Analysis Procedures Paragraph 4.3 - Use of the word "calibration" may be confusing in this section. TVA recommends use of the word "standardization" when a daily response is produced using purchased liquid reference material such as pH buffers or conductivity standards and the like.
(b) Response: "Calibration" is defined in appendix B of the Manual as the "comparison of a measurement standard, instrument or item with a standard or instrument of higher accuracy to detect and quantify inaccuracies and to report or eliminate those inaccuracies by adjustments." The Cabinet believes that the use in Chapter II Section 4.3 of the word "calibration," as defined, is an appropriate use of this term.

(55) Subject Matter: Clarification of PT requirements
(a) Commenter: John Myers, TVA
Comment: Section II Section 5.0 Proficiency Testing (PT) Requirements and Frequency Paragraph 5.1 - For clarity, TVA suggests re-wording the last sentence to read "A certified laboratory shall purchase PT samples(s) from a provider approved by the American Association for Laboratory Accreditation."
(b) Response: The Cabinet agrees that the rewording suggestion simplifies this sentence and has changed the wording in Chapter II Section 5.1 of the Manual as suggested.

(56) Subject Matter: PT failure clarification
(a) Commenter: John Myers, TVA
Comment: Paragraph 5.5 - Clarify whether all certification is withdrawn or only that for the single analyte missed on the PT study is withdrawn. Example: If hardness (Mg+Ca) by ICP is missed, would one lose all inorganic analyte accreditation, all hardness certification, or just hardness by that one method?
(b) Response: Section 10 (2) of the proposed administrative regulation, as amended states: "If the status is changed to provisional certification, this changed status shall be for only the analyte that failed to meet the requirements of Section 11 (2) of this administrative regulation, unless the cabinet had certified a group of related analytes based on a limited number of analytes in the group." Therefore, if certification had been approved for a group of analytes in this manner, the Cabinet would have discretion in determining the appropriate extent of the provisional certification.

(57) Subject Matter: Sampler contact information
(a) Commenter: John Myers, TVA

Comment: Section 6.0 Report Requirements and Record Keeping Paragraph 6.4.1 - Suggest changing "& phone number of the sampler" to "and contact information".

(b) Response: The Cabinet believes that it is appropriate to specify what contact information is the most useful rather than leave it up to the discretion of the individual sampler. If the Cabinet has questions regarding a sample, a phone number is generally more useful than any other type of "contact information" that a sampler may have provided in the space for information.

(58) Subject Matter: Quality control analysis vs. quality control sample

(a) Commenter: John Myers, TVA

Comment: Chapter II 6.5.4 (of the Manual) - Suggests changing to "quality control sample analysis"

(b) Response: Quality control sample is only one specific analysis and does not encompass all required quality control analysis. Analytical records must contain all quality control analyses (e.g. Method blank, CCV, LCS, QCS, MS, etc.) not just the quality control sample.

(59) Subject Matter: Traceability requirements

(a) Commenter: John Myers, TVA

Comment: Paragraph 6.5.5 - Suggest adding "including concentrations and expiration dates of calibration standards and traceability to nationally recognized standard materials."

(b) Response: Chapter II Section 8.8 of the Manual states that "calibrations of measurement devices shall be traceable to national standards, if applicable." The Cabinet does not believe that it is necessary to insert the commenter's suggested language into Chapter II Section 6.5.5. Regarding adding the phrase "including concentrations and expiration dates of calibration standards," the Cabinet agrees that this suggestion identifies some of the required analytical records. However, there are other analytical records required, and inserting only a partial list could be interpreted as the records not listed were not required. Therefore, the Cabinet has not changed the Manual in response to this comment.

(60) Subject Matter: Software verification requirements

(a) Commenter: John Myers, TVA

Comment: Paragraph 6.7 - Meaningful testing of most chemical workstation software (example: gas chromatography workstation software which identifies peaks, performs calibration curves, and calculates analytical concentrations) is beyond the ability of the average commercial laboratory. TVA suggests limiting initial verification of computer programs only to those written by the laboratory to manipulate data.

(b) Response: The Cabinet believes that it is important for a wastewater laboratory to be able to verify how a computer program is making calculations or, at the very least, that the program is operating properly. The Cabinet acknowledges that the laboratory staff may not have access to program code from purchased software. These programs are verified through the analysis of standards and verifying accuracy of results received from the software's calculations.

(61) Subject Matter: Clarification of certification requirements
(a) Commenter: John Myers, TVA
Comment: Chapter II Section 7.3 (of the Manual) - Suggest changing third bullet to "QC sample results"
(b) Response: Quality control sample is only one specific analysis and does not encompass all required quality control analysis. Analytical records must contain all quality control analyses (e.g. Method blank, CCV, LCS, QCS, MS, etc.) not just the quality control sample.

(62) Subject Matter: Clarification of equipment requirements
(a) Commenter: John Myers, TVA
Comment: Chapter II Section 8.3.2 (of the Manual) - Rephrase to "against a reference thermometer traceable to the National Institute . . . etc.
(b) Response: The Cabinet believes that both the suggested wording and the current wording in Chapter II Section 8.3.2 of the Manual for this requirement would be acceptable; therefore no change to the Manual has been made.

(63) Subject Matter: Class A volumetric standard
(a) Commenter: John Myers, TVA
Comment: Paragraphs 8.5.3 through 8.5.5 - Class A glassware is good to within 0.2% (see Fritz and Schenk, 1974 and ASTM E288). It is troubling to allow 2.5% but still call it Class A.
(b) Response: The Cabinet agrees and has removed the phrase "shall be calibrated annually and adjusted or replaced if the precision or accuracy is greater than 2.5%" from Chapter II Section 8.5.4 of the Manual. Section 8.5.4 will be replaced with "All pipets shall meet the requirements of their applicable use." For purposes of consistency, the Cabinet has removed the reference to Class A in Chapter II Section 8.5.3 of the Manual, leaving the requirement that glass and plastic pipets delivering volumes of 10 ml or less shall be accurate to within a precision of 2.5%.

(64) Subject Matter: Daily pipette checks
(a) Commenter: John Myers, TVA
Comment: Suggest adding a new paragraph 8.5.6 to read "All manual auto-pipettes shall be checked daily, each day of use and, when

adjustable, after each adjustment, by weighing deionized water to ensure the volume delivered is within tolerances."

(b) Response: The Cabinet believes that the added benefit from a daily check would be insufficient to justify the resources need to implement this procedure within the laboratories. Chapter II Section 8.5.5 under the revised manual contains requirement for a quarterly check and these requirements provide sufficient documentation of compliance.

(65) Subject Matter: Quality assurance vs. quality control

(a) Commenter: John Myers, TVA

Comment: Section 9.0 Quality Assurance / Quality Control Paragraph 9.0 - Throughout change "Quality Assurance/Quality Control" to simply "Quality Control". Likewise "QA/QC" to "QC"

(b) Response: "Quality Assurance" and "Quality Control" have two distinct definitions. See Appendix B, Page 7, of the Manual.

(66) Subject Matter: Corrective action (root cause analysis)

(a) Commenter: John Myers, TVA

Comment: Paragraph 9.2.3.9 - Corrective action is not identical to root cause analysis. TVA suggests dropping the latter.

(b) Response: 40 CFR 136.7 (c)(1)(ix) lists "Corrective action (root cause analysis)" as one of the 12 elements of quality control that must be accounted for by the laboratory. Therefore, the Cabinet has not made a change to the manual.

(67) Subject Matter: Chain of custody

(a) Commenter: John Myers, TVA

Comment: Section 12.0 Data Management Paragraph 12.1.7.3 - TVA suggests also including the condition of or absence of custody seals to this requirement.

(b) Response: The Cabinet believes that a properly used Chain of Custody with signatures for sample relinquishment and receipt is adequate, and that a requirement for custody seals is not needed. Therefore, the Cabinet has not made a change to the manual.

(68) Subject Matter: Sample storage contamination

(a) Commenter: John Myers, TVA

Comment: Section 2.0 Laboratory Facility & Safety Paragraph 2.0 - Suggest adding text "Highly contaminated samples should be segregated from others."

(b) Response: It is not clear to the Cabinet how a wastewater laboratory would know if a sample is "highly contaminated." Section 2.0 states that the "sample storage area shall be isolated from all potential sources of contamination." If a laboratory were to know that a sample is contaminated prior to actual analysis, then the contaminated

sample would be required to be kept isolated from the other samples in the sample storage area. In addition, "highly contaminated samples" is vague and not enforceable. However, the Cabinet agrees this is a good lab practice to prevent cross contamination.

(69) Subject Matter: Maintenance logs
(a) Commenter: John Myers, TVA
Comment: Section 3.0 Laboratory Equipment and Instrumentation Paragraph 3.0 - Suggest changing last sentence to read: "Requirements for maintenance logs shall be included in the laboratory's Quality Assurance Plan."
(b) Response: The Cabinet agrees and has made the suggested change in Chapter III Section 3.0 of the Manual.

(70) Subject Matter: Clarification of quality control phrasing
(a) Commenter: John Myers, TVA
Comment: Section 4.0 General Chemistry Laboratory Practices Paragraph 4.3 - Suggest changing text "and quality control criteria" to read "and quality criteria".
(b) Response: "Quality control" is the phrase used to signify the overall system of technical activities to measure and control the quality of a service. Therefore, the Cabinet believes that this phrase in Chapter III Section 4.3 is used appropriately as an adjective to describe the criteria specified in the methods that are required.

(71) Subject Matter: Sample collection procedures
(a) Commenter: John Myers, TVA
Comment: Chapter IV, Section 5.0 Sample Collection, Handling and Preservation Paragraph 5.0 - Suggest adding language to assure that this requirement is not applied when the laboratory is not involved in sample collection.
(b) Response: Sample collection requirements are part of the KPDES permit. Sample collection must be conducted in compliance with the applicable requirements of the methods identified in 40 CFR Part 136. Collection of compliance samples is not subject to the requirements of the WLCP and compliance sample collection is not subject to audit under the WLCP. The notable exception to this being field analysis. If the person collecting KPDES compliance samples is also conducting field analyses as defined in the proposed administrative regulation, that person must be associated with a wastewater laboratory certified for Field Analysis. The requirements in the Manual apply only to laboratories certified pursuant to this administrative regulation. Therefore, the Cabinet has not made any changes to the Manual.

(72) Subject Matter: MRL definition
(a) Commenter: John Myers, TVA
Comment: Section 7.0 Quality Control Acceptance Criteria and Calculations Paragraph 7.1.2 - The acronym MRL is not defined before this point.
(b) Response: The Cabinet agrees and has added the term "Minimum Reporting Level" followed by (MRL) to Chapter III Section 7.1.2 of the Manual.

(73) Subject Matter: Linear calibration clarifications
(a) Commenter: John Myers, TVA
Comment: Paragraph 7.4 Instrument Calibration - "Linear calibration curve (linear regression) shall be calculated as follows:" does not provide the actual calculations. Further, x should be the instrument response and y the concentration. Suggest replacing the sentence and box with "Linear calibration curves are often fit to the form y = mx + b where m is the slope, x is the instrument response, y is the concentration, and b is the y intercept." Then the following sentences "Other equation forms may be acceptable." Strictly speaking, "linear regression" is the mathematical technique associated with many equation forms and is not limited to "y = mx + b". Consequently the final sentence might be better "If utilizing another equation for, the laboratory shall ensure . . . ".
(b) Response: The Cabinet acknowledges that the suggested calculation would be acceptable. However, the Cabinet believes that the calculation and definitions of the terms in the equation as written in Chapter III Section 7.4 of the Manual is the preferred format. The Manual allows for other formats to be used, provided that they are demonstrated to meet the method data objectives.

(74) Subject Matter: RRL definition
(a) Commenter: John Myers, TVA
Comment: Appendix B - Required Reporting Limit (RRL) is not defined.
(b) Response: The Cabinet agrees and to clarify has added a definition of "Required Reporting Limit" to Appendix B of the Manual.

(75) Subject Matter: Regulation cost
(a) Commenters: Tyler Campbell, KLC; Annette DuPont-Ewing, KMUA
Comment: The purpose of KRS 224.10-670 is to provide for an efficient method to ensure that entities submitting data pursuant to a KPDES permit could rely on the accuracy of data being provided by laboratories. The purpose was not to create a new bureaucracy. KLC believes that the proposed program should be streamlined to allow for a non-duplicative set of standards that are appropriate to the type of laboratory being operated. The statute does not mandate that the certification be so difficult as to force

municipalities to either close their laboratories for which substantial funds have already been spent or incur additional costs. Not counting the addition of necessary personnel due to the regulation, even small to medium size municipal wastewater laboratories will likely face increased costs between $12,000-$15,000 annually to comply with the proposed regulation. In terms of the personnel and time it will take to run additional quality controls tests, many city-owned labs are looking at potential additional costs of $30,000. This will likely have the effect of forcing cities to mothball existing expensive infrastructure and outsource laboratory services. This program will be a tremendous burden on already strained municipal budgets and may actually result in less process control for wastewater operations. This legislation has the potential to cost $12-15,000 just in purchasing the chemical NIST standards information. The DOW has yet to stipulate which standards it will use – again uncertainty. The parameters of the program will affect the process control element of the laboratory work. This program is not only complex and expensive but cumbersome to comply with. It's the worst kind of regulation – the kind that sacrifices good, well trained personnel with expertise while the work is pushed out – because of new costs and constraints – to commercial laboratories.

(b) Response: The cabinet appreciates the comment and has, as much as possible, taken every effort to minimize the cost and regulatory burden of the program. Other than requiring certification of wastewater laboratories, the proposed regulation, as amended, does not impose any additional requirements beyond the requirements of 40 CFR Part 136, which already apply to Clean Water Act §402 (NPDES) compliance data. In that regard, the operational costs associated with compliance with the WLCP other than those costs realized with certification fees, should not be new costs, but actual costs already realized by the requirement to comply with 40 CFR 136.

In consideration of the smaller municipal wastewater laboratories, the Cabinet included tiering of fees, but recognizes that the federal requirements do not change based upon the size of the wastewater laboratory. Additionally, the Cabinet believes that field analyses should be viewed and treated differently than the more complex analyses conducted in a laboratory. In that regard, the Cabinet has proposed to simplify the certification process for "Field Only" wastewater laboratories. The cabinet is developing SOP and QAP templates to assist facilities in obtaining "Field Analysis Only" certification. A KPDES permitted facility that is providing field analyses for its own facility is exempt from certification fees in accordance with this regulation. The proposed administrative regulation, as amended, also provides a 20% reduction of

certification fees for a wastewater laboratory obtaining equivalency of certification.

Chapter II Section 8.8 of the Manual states that laboratories must use standards that are "traceable." As long as a standard being used has a Certificate of Authenticity, that standard is considered a "traceable standard."

The WLCP does not apply to analyses performed for process control. Analysis of effluent samples taken for internal operation information is not subject to the federal requirements of 40 CFR Part 136, nor is the analysis required to be performed by a certified laboratory pursuant to 401 KAR 5:320.

(76) Subject Matter: DMR-QA and certification program duplication

(a) Commenter: Tyler Campbell, KLC

Comment: KLC believes that the duplication of regulation inherent in the proposed regulation is unnecessary and an unwise use of public funds. Many of our cities in Kentucky have programs in place that meet the requirements for laboratories set forth in the KPDES program. KLC would like to emphasize that the authorizing statute does not require the Division to "reinvent the wheel." If there is a program in place that meets the needs of the Division, it should be utilized to allow certification of laboratories rather than putting them through a duplicative process. Consequently, KLC urges the Division to amend the proposed regulation to allow any permittee that participates in the DMR-QA program to automatically be considered certified under the laboratory certification regulations.

(b) Response: The Cabinet appreciates the concern raised regarding duplication of effort, however the Cabinet believes this regulation is necessary to ensure the reliability of laboratory data being provided for purposes of compliance pursuant to U.S.C 1342. The proposed administrative regulation, as amended, does not include an exemption for a facility participating in EPA's DMR-QA program. However, the Cabinet intends to request approval from EPA to implement the DMR-QA program in Kentucky. If approved, the EPA's DMR-QA program would be subsumed by the WLCP, and a KPDES permit holder would no longer be required to demonstrate compliance with the EPA's DMR-QA program

(77) Subject Matter: Municipality fees

(a) Commenter: Tyler Campbell, KLC

Comment: The Division's proposed regulation seeks to tier the fee schedule for municipal systems. While KLC appreciates the consideration, KLC believes that all fees should be waived for municipalities. It

is improper for one government entity to tax another. The taxpayers are already paying for compliance at the local level. They should not be asked to pay for state review of the same thing. This has already been recognized by the General Assembly as it related to fees associated with the KPDES program.

(b) Response: The Cabinet has, as much as possible, made every effort to minimize the cost and regulatory burden of the program, including tiering fees for municipalities. The cabinet established the fee schedule based on its cost to administer the program. KRS 224.10-670 provides that the cabinet may promulgate administrative regulations establishing "… fees for certification..." The authorizing statute does not restrict the cabinet from charging fees to municipalities for this certification.

(78) Subject Matter: Pretreatment requirements

(a) Commenter: Tyler Campbell, KLC

Comment: KLC is perplexed as to how this program interacts with pre-treatment program requirements. Municipalities are required to maintain pre-treatment programs under the KPDES regulations. Are municipalities obligated to enforce laboratory certification requirements for dischargers to their systems? If so, it would be an additional burden with which municipalities would have difficulty complying.

(b) Response: The requirements of the proposed administrative regulation, as amended, do not apply to analyses of samples from pretreatment facilities that discharge to a wastewater treatment plant.

(79) Subject Matter: KAM laboratory certification program approval

(a) Commenter: Rusty Cress, KAM

Comment: KAM appreciates the Division's pro-active approach in attempts to building a consensus among stakeholders that could be impacted by the proposed regulation.

(b) Response: The Cabinet acknowledges the comment.

(80) Subject Matter: KAM electronic file approval

(a) Commenter: Rusty Cress, KAM

Comment: KAM supports the provisions allowing all documents required pursuant to the program to be kept electronically.

(b) Response: The Cabinet acknowledges the comment.

(81) Subject Matter: Statutory authority and regulation duplication

(a) Commenter: Rusty Cress, KAM

Comment: KAM and other stakeholders have been engaged in the development of the regulation and hope that the Division will address the concerns set forth below which have not been previously addressed. Furthermore, KAM urges the Division to be

mindful of its statutory authority for promulgating the proposed regulation. The Energy and Environment Cabinet is authorized to promulgate regulations establishing:
(a) Standards for the *operation of laboratories* relating to analyses and laboratory tests for wastewater pollution, on behalf of activities subject to 33 U.S.C. sec. 1342, fees for certification and competency evaluations of those laboratories, and issuance of certificates of competency to persons and laboratories meeting the standards established by the agency; and
(b) A *certification program for laboratories* that submit environmental data as it relates to analyses and laboratory tests for activities subject to 33 U.S.C. sec. 1342. In developing the certification program, the cabinet shall consider, among other things, nationally recognized certification programs and those tailored for individual states.
The General Assembly's purpose in enacting KRS 224.10-670 was to provide for an efficient method to ensure that entities submitting data pursuant to a KPDES permit could rely on the accuracy of data being provided by laboratories. The purpose was not to create a new bureaucracy within an already complicated environmental regulatory program. Consequently, KAM requests that the proposed program be streamlined to allow for a non-duplicative set of standards that are only applicable to laboratories.

(b) Response: The Cabinet appreciates the comment and agrees that it is obligated to operate the program within its authorized statutory authority. The Cabinet also agrees that the WLCP should be efficient and not duplicative of existing requirements. The cabinet has taken every effort to minimize costs for the program; the fee structure is designed to cover only the cost for the Cabinet to operate the program, and to minimize the regulatory burden of the program.

Other than requiring certification of wastewater laboratories, the proposed administrative regulation, as amended, does not impose any additional requirements beyond the requirements of 40 CFR Part 136, which already apply to Clean Water Act §402 (NPDES) compliance data. However, the Cabinet believes that field analyses should be viewed and treated differently than the more complex analyses conducted in a laboratory. In that regard, the Cabinet has proposed to simplify the certification process for "Field Only" wastewater laboratories. The cabinet is developing SOP and QAP templates to assist facilities in obtaining "Field Analysis Only" certification. A KPDES permitted facility that is providing field analyses for its own facility is exempt from certification fees in accordance with this regulation. It is also important to note that process-control analyses are not subject to this regulation.

(82) Subject Matter: Labs that analyze a minimal number of samples per year

(a) Commenter: Rusty Cress, KAM

Comment: Consideration must be given to laboratories that analyze a minimal number of samples per year. It is suggested that a tiering approach be applied to address these issues. As part of this suggestion, if the KPDES program or 40 CFR Part 136 require or authorize certain methods to be utilized for field sampling, the regulated entity should only be required to show the Division that it is in compliance with those requirements. For example, any permittee participating in the DMR-QA program, along with making other minor, ministerial showings should be considered to be certified.

(b) Response: The cabinet has made every effort to minimize the regulatory burden of the program. Other than requiring certification of wastewater laboratories, the proposed regulation, as amended, does not impose any additional requirements beyond the requirements of 40 CFR Part 136, which already apply to Clean Water Act §402 (NPDES) compliance data. In consideration of the smaller municipal wastewater laboratories, the Cabinet included tiering of fees, but recognizes that the federal requirements do not change based upon the size of the wastewater laboratory. Additionally, the Cabinet believes that field analyses should be viewed and treated differently than the more complex analyses conducted in a laboratory. In that regard, the Cabinet has proposed to simplify the certification process for "Field Only" wastewater laboratories. The cabinet is developing SOP and QAP templates to assist facilities in obtaining "Field Analysis Only" certification. A KPDES permitted facility that is providing field analyses for its own facility is exempt from certification fees in accordance with this regulation. It is also important to note that process-control analyses are not subject to this regulation. The proposed administrative regulation, as amended, does not provide an exemption from the requirements of this regulation for a facility participating in the EPA's DMR-QA program. The Cabinet intends to request approval from EPA to implement the DMR-QA program in Kentucky. If approved, the EPA's DMR-QA program would be subsumed by the WLCP, and a KPDES permit holder would no longer be required to demonstrate compliance with the EPA's DMR-QA program. The proposed administrative regulation, as amended, does provide a 20% reduction of certification fees for a wastewater laboratory obtaining equivalency of certification.

(83) Subject Matter: Excess Requirements

(a) Commenter: Rusty Cress, KAM

Comment: While not endorsing any particular existing certification program, KAM believes that any requirement contained in the proposed

regulation and associated documents that are in excess of requirements imposed under nationally-recognized accreditation program should be removed.

(b) Response: Other than requiring certification of wastewater laboratories, the proposed regulation, as amended, does not impose any additional requirements beyond the requirements of 40 CFR Part 136, which already apply to Clean Water Act §402 (NPDES) compliance data.

The proposed regulation recognizes other national accreditation standards, such as NELAC, and provides that laboratories certified under other accreditations can seek certification in accordance with this regulation via the "equivalency of certification" provision in Section 1(3) "Equivalency of certification," which means certification of a wastewater laboratory by an entity, other than the cabinet, whose requirements for certification are determined by the cabinet to meet the requirements of this administrative regulation.

(84) Subject Matter: Definition of "Wastewater laboratory" and pretreatment facilities

(a) Commenters: Rusty Cress, KAM; Fanto Bayo, City of Frankfort; Chad Harpole, Kentucky Chamber of Commerce

Comment: Section 1(7) defines "Wastewater laboratory" as a laboratory that performs an analysis or laboratory test for an activity subject to 33 U.S.C. 1342. For the purposes of this regulation, the definition should be clarified to state that the definition only applies to laboratories analyzing data that is submitted for purposes of determining compliance with a Section 402 permit and does not apply to analyses and laboratory tests performed for any other purpose including but not limited to any analyses or laboratory test conducted pursuant to other Clean Water Act permits, certification, approvals, or requirements. Section 2 should be clarified in a similar fashion. In addition, the regulation should make it clear whether industries that are monitored under a pretreatment program would have to ensure they contract a Kentucky-certified laboratory to analyze their wastewater samples. Several industries do have laboratories outside the state that do their lab analyses.

(b) Response: The Cabinet agrees that Section 3 of the proposed administrative regulation, as amended, is clarified by adding "to the cabinet" after "submitted" and has made this change to Section 3. KRS 224.10-670 applies to "…activities subject to 33 U.S.C. 1342;" applying to KPDES-permitted facilities that discharge into the waters of the Commonwealth. KRS 224.10-670 (2) includes the qualification "… data submitted … to any agencies of the cabinet …" Section 3 of the proposed administrative regulation, as amended, states in part, "… environmental data … submitted for activities subject to 33 U.S.C. 1342, shall be performed … by a certified wastewater laboratory …" Thus, the Cabinet agrees that the definition applies

only to wastewater laboratories that analyze data that are submitted for purposes of determining compliance with a Section 402 permit. This does not include pretreatment facilities that discharge to a wastewater treatment facility, because the results of effluent samples are not required to be submitted to the Cabinet.

(85) Subject Matter: Field Sample Analysis

(a) Commenter: Rusty Cress, KAM

Comment: Regulation of Field Sample Analysis_KAM requests that the Division simplify the regulation of field sample analysis necessary under the KPDES permit. The requirements in the regulation and related documents related to field analysis, which should be a fairly uncomplicated certification or acknowledgement process, continue to be unnecessarily burdensome. The "certification" necessary under KRS 224.10-670 does not require a full-blown world class laboratory demonstration. There are basic measures taken in field sample activities and those should be sufficient to meet the certification requirements in the statute. There is far too great an opportunity for unnecessarily duplicative regulation in the current version of the proposed regulation.

(b) Response: The cabinet appreciates the comment and has, as much as possible, taken every effort to minimize the cost and regulatory burden of the program. Other than requiring certification of wastewater laboratories, the proposed regulation, as amended, does not impose any additional requirements beyond the requirements of 40 CFR Part 136, which already apply to Clean Water Act §402 (NPDES) compliance data. However, the Cabinet believes that field analyses should be viewed and treated differently than the more complex analyses conducted in a laboratory. In that regard, the Cabinet has proposed to simplify the certification process for "Field Only" wastewater laboratories. The cabinet is developing SOP and QAP templates to assist facilities in obtaining "Field Analysis Only" certification. A KPDES permitted facility that is providing field analyses for its own facility is exempt from certification fees in accordance with this regulation. It is also important to note that process-control analyses are not subject to this regulation.

(86) Subject Matter: Field Sample Analysis

(a) Commenter: Rusty Cress, KAM

Comment: KAM fully supports the Division's inclusion of Section 6(9), which states that a "wastewater laboratory operated by a facility that has been issued a Kentucky Pollutant Discharge Elimination System permit and that is providing only field analysis for only its own facility shall be exempt from all fees established in this administrative regulation."

(b) Response: The Cabinet acknowledges the comment.

(87) Subject Matter: Field Sample Analysis
(a) Commenter: Rusty Cress, KAM
Comment: The requirements associated with Section II, 4.1 of the Wastewater Laboratory Certification Manual ("Manual") are not authorized by KRS 224.10-670.
(b) Response: The Cabinet appreciates the concern and is revising Chapter II Section 4.1 of the Laboratory Manual to remove the requirements that address field sampling. Sample collection must be conducted in compliance with the facility's KPDES permit, required QAP and the applicable requirements in the methods identified in 40 CFR Part 136. The notable exception to this being field analysis. If the person collecting KPDES compliance samples is also conducting field analyses as defined in the proposed administrative regulation, that person must be associated with a wastewater laboratory certified for Field Analysis.

(88) Subject Matter: Field Sample Analysis
(a) Commenter: Rusty Cress, KAM
Comment: In previous conversations, the Division has indicated that it believes laboratories performing field sampling activities should be held to higher standards.
(b) Response: The Cabinet intent is to hold accountable those performing field sampling activities to comply with the standard methods outlined in 40 CFR 136. The proposed administrative regulation does not require that the person collecting compliance samples in accordance with the KPDES permit be associated with a certified wastewater laboratory. Sample collection requirements are part of the KPDES permit. Sample collection must be conducted in compliance with the permit, including the required QAP and the applicable requirements of the methods identified in 40 CFR Part 136. The notable exception to this being field analysis. If the person collecting KPDES compliance samples is also conducting field analyses as defined in the proposed administrative regulation, that person must be associated with a wastewater laboratory certified for Field Analysis.

(89) Subject Matter: Field Sample Analysis
(a) Commenter: Rusty Cress, KAM
Comment: After an analysis of the ramifications associated with these requirements, KAM is of the belief that this provision would, in essence, eliminate the practice of field sample collection by consultants and other contracted entities. KAM strongly urges the Division to eliminate Section 4.1 and amend Section 4.2 to read: "An employee of***, or person under contract with***, a permitted facility may perform the following field analyses…."

(b) Response: Collection of compliance samples is not subject to the requirements of the WLCP and is not subject to audit under the WLCP. The proposed administrative regulation does not require that the person collecting compliance samples in accordance with the KPDES permit be associated with a certified wastewater laboratory. Sample collection requirements are part of the KPDES permit. Sample collection must be conducted in compliance with the permit, including the required QAP, and applicable requirements of the methods identified in 40 CFR Part 136. The notable exception to this being field analysis. If the person collecting KPDES compliance samples is also conducting field analyses as defined in the proposed administrative regulation, that person must be associated with a wastewater laboratory certified for Field Analysis.

(90) Subject Matter: Field Sample Analysis

(a) Commenter: Rusty Cress, KAM

Comment: In Section II, 7.1.4 of the Manual, related to MDLs associated with field analysis, a document is referenced to be available on the Division's web site entitled Combined RRL List for Laboratories. KAM is having difficulty locating the appropriate information at that location for Total Residual Chlorine and any corresponding performance requirements. It is recommended that this information be updated and included directly in the Wastewater Laboratory Certification Manual.

(b) Response: The Cabinet was not able to locate the reference to this document in the Manual.

(91) Subject Matter: Field Sample Analysis

(a) Commenter: Rusty Cress, KAM

Comment: KAM also requests that, upon the initial demonstration of compliance for field parameters, the entity would be exempt from future activities. The Division currently conducts annual CEI audits, reviewing data and plans.

(b) Response: The Cabinet believes that passing a one-time, on-site audit does not ensure that the wastewater laboratory will continue to comply with all requirements in perpetuity. However, the Cabinet believes that field analyses should be viewed and treated differently than the more complex analyses conducted in a laboratory. In that regard, the Cabinet has proposed to simplify the certification process for "Field Only" wastewater laboratories. The cabinet is developing SOP and QAP templates to assist facilities in obtaining "Field Analysis Only" certification. A KPDES permitted facility that is providing field analyses for its own facility is exempt from certification fees in accordance with this regulation. It is also

important to note that process-control analyses are not subject to this regulation.

(92) Subject Matter: Equivalency of certification
(a) Commenter: Rusty Cress, KAM
Comment: Equivalency of certification is defined in the regulation, but is only mentioned as it relates to fees. It does, however, show up in the application in great detail. The Division is creating far more work than is necessary in these situations. The definition of "equivalency of certification," as well as any requirements related to it in the associated documents, should be revised to accept the equivalency certification without the need to go through an entirely new certification process for Kentucky. The only requirements should be that the applicant submits proof of certification and details regarding the program under which the applicant is certified.
(b) Response: The Cabinet believes that this information is necessary to make a determination as to whether the applicant laboratory meets the requirements of this administrative regulation and that this information is otherwise readily available to the applicant.

(93) Subject Matter: Fee for equivalency of certification
(a) Commenter: Rusty Cress, KAM
Comment: Laboratories seeking equivalency of certification will require much less work on the part of the Division and should be required to pay much less than the 80% set forth in the regulation.
(b) Response: The Cabinet has, as much as possible, taken every effort to minimize the cost and regulatory burden of the program. The administration of this program for a laboratory certified under the equivalency provision is not significantly less than for other laboratories. Therefore, the Cabinet has not changed the regulation in response to this comment.

(94) Subject Matter: Annual payment of fees
(a) Commenter: Rusty Cress, KAM
Comment: The term for certification is stated to be 2 years. Section 6, related to Annual Certification Fees, should correspond to the certification renewal period and be due every two years.
(b) Response: At the request of several stakeholders, the Cabinet provided in the regulation that a certified lab could pay fees annually, even though certification is for a two-year period.

(95) Subject Matter: Quality Assurance Plans (QAPs)
(a) Commenter: Rusty Cress, KAM
Comment: Quality Assurance Plans. In Section 3.0 of the Manual, a Quality Assurance Plan is required to be a "stand alone" document. This is

inconsistent with contemporary day to day use of technology in the due course of normal business activities. Access to manuals, SOPs, and similar documents no longer depends on the assimilation of these documents into a three ring binder. The application of this outdated methodology is impractical and ineffective with respect to document access, management, revision and control.

(b) Response: The Cabinet agrees that today's technology provides options other than printed documents contained in a three-ring binder. The Manual does not require that the QAP be printed and put into a three-ring binder. The QAP must be a stand-alone document, which may be kept electronically.

(96) Subject Matter: Quality Assurance Plans

(a) Commenter: Rusty Cress, KAM

Comment: KAM believes that the requirement to submit the QAP to the Division with the application (particularly for laboratories conducting only field analysis for their own discharge), and with all subsequent significant revisions is impractical and superfluous. KAM urges the Division to only require a certification that the laboratory has and maintains a QAP, has and maintains SOPs for all analysis conducted, that these documents be reviewed at least annually by a laboratory supervisor and the analysts who perform the analysis, and that it be maintained in an orderly fashion for efficient and effective review by the Division at any time during normal business hours.

(b) Response: The purpose of submitting the wastewater laboratory's QAP is for the Cabinet to review the document to ensure that it meets all of the WLCP requirements. Interim certification will be determined based upon a review of an applicant's submitted documents, including the QAP. The biannual application is required to include identification of any changes to the QAP. Reviewing the entire documents while doing an on-site audit would not be an efficient use of time in the field for the Cabinet's auditors. If a laboratory has and maintains a QAP in an orderly fashion, the Cabinet does not consider it to be impractical to submit a copy with the initial application and biannually submit subsequent changes.

(97) Subject Matter: Training Manual

(a) Commenter: Rusty Cress, KAM

Comment: Part II, Section 2.0 -- The Section states that analyst training records shall include all MDL studies, IDCs, DOCs, etc. Typically, MDL studies are performed per instrument and not necessarily per analyst. The MDL study should not document per analyst for every method.

(b) Response: The Cabinet agrees that an MDL study is not required to be performed by every analyst. However, if an analyst has performed an MDL study for compliance with the certification program, the results of that study shall be kept on file and be readily available in that analyst's records.

(98) Subject Matter: Training Manual

(a) Commenter: Rusty Cress, KAM

Comment: Part II, Section 3.3.4 -- The Section requires annual review of SOPs. Typically, frequency of review of SOPs is set by a laboratory's requirements in their Quality Assurance Manual. The Section should be amended to allow for the review to occur consistent with the Quality Assurance Manual.

(b) Response: The Cabinet believes that a standard annual period for this review is reasonable. It is the Cabinet's experience with wastewater laboratories that minor changes occur frequently and that an annual review of the SOP is reasonable. If no change has been made since the last review, then a simple sign off is all that is necessary. Therefore, no changes to the manual have been made in response to this comment.

(99) Subject Matter: Training Manual

(a) Commenters: Rusty Cress, KAM; Robin Strader, Leitchfield Wastewater Treatment Plant and KLA

Comment: Part III, Section 1.0 -- The Section speaks of Alternate Test Procedure Methods, and that a signed copy of the ATP from the EPA shall be maintained by the laboratory. As of the March 12, 2007, EPA Methods Update Rule (MUR), the EPA no longer requires laboratories to have a letter on file. This MUR allowed the regulated community more flexibility to modify approved methods without EPA review as long as the modification documentation follows the procedure in 40 CFR 136.6.
As proposed, each facility will have to secure and maintain ATP documentation. It would be more efficient if the certification officials maintained the ATP and everyone had access to them as a reference.

(b) Response: Only the EPA has the authority to approve an alternate method via the Alternate Test Procedure. Regardless of whether this is done for nationwide use pursuant to 40 CFR 136.4 or for limited use pursuant to 40 CFR 136.5, approval by an individual wastewater laboratory is done on a case-by-case basis. In that this is done on a case-by-case basis, an efficient way for the Cabinet to know if approval was granted to use an ATP is for the individual wastewater laboratory to maintain a copy of the approval from the EPA. Therefore, the Cabinet respectfully disagrees that a wastewater laboratory, for which an ATP is approved by the EPA,

should not be required to maintain a copy of the EPA's ATP approval until such time as the EPA approves the ATP as an accepted method listed in 40 CFR Part 136. However, the Cabinet notes that a method may be used if it is specified in an approved KPDES permit, the approval of which undergoes review by the EPA.

(100) Subject Matter: Impact of regulation

(a) Commenter: Robin Strader, Leitchfield Wastewater Treatment Plant and KLA

Comment: The title, "Wastewater Laboratory Certification Program", implies or is viewed by most managers and operators as the place they send samples to for analysis. Yet when reading the document, it will impact every permitted facility in the state including water plants with backwash lagoons because the program goes all the way back to sample collection. As far as certified water and wastewater operators certified under the Kentucky Division of Compliance Assistance, operators are trained and tested on sample collection and discharge requirement. It is estimated that 20% of the wastewater certification exam covers laboratory analysis, sampling and discharge requirements. Therefore, imposing an additional need for this certification on operators would devalue Kentucky's licensed operator and cast a dim light on Kentucky's excellent operator certification program. Additionally, water operators routinely collect samples for drinking water compliance and analyze samples for monthly operator reports submitted to the Division of Water with no need for additional "field" certification.

(b) Response: The Cabinet appreciates the comment and has, as much as possible, taken every effort to minimize the cost and regulatory burden of the program. KRS 224.10-670 requires the Cabinet to establish a "certification program for laboratories that submit environmental data as it relates to analyses and laboratory tests for activities subject to 33 U.S.C. sec. 1342, includes standards for the operation of laboratories, fees for certification and competency evaluations, and the issuance of certificates of competency. Based upon investigations the Cabinet has conducted of laboratories in Kentucky conducting wastewater monitoring and testing services, the Cabinet has determined that quality control and quality assurance procedures at some wastewater laboratories are inadequate, in part, due to a lack of clear regulatory standards and certification programs for wastewater laboratories. The intent of the wastewater laboratory certification program is to ensure that the integrity of KPDES compliance data can be ascertained. The Cabinet has, as much as possible, taken every effort to minimize the cost and regulatory burden of the wastewater laboratory certification program. The wastewater laboratory certification program is applicable to all labs conducting KPDES compliance

data analysis; the authorizing statute does not exempt analysis of compliance data conducted by certified water or wastewater operators from the requirements of the statute or authorized regulation.

(101) Subject Matter: Application due dates

(a) Commenter: Robin Strader, Leitchfield Wastewater Treatment Plant and KLA

Comment: The certification applications being due on even numbered years could be confusing for certified operators because all wastewater renewals are due in odd numbered years.

(b) Response: The Cabinet appreciates the concern and has amended Section 7 of the proposed regulation. The renewal applications for general wastewater laboratories are now due to the cabinet by November 15 of the odd-numbered year. Renewal applications for Field-Only Wastewater Laboratories are due by November 15 of the even-numbered year. The Cabinet intends to notify the certified wastewater laboratories via e-mail reminding them of an upcoming renewal application due date, provided that a current e-mail address is on file with the Cabinet. The responsibility of submitting a timely renewal application rests with the wastewater laboratories.

(102) Subject Matter: Fees and documentation submittal

(a) Commenter: Robin Strader, Leitchfield Wastewater Treatment Plant and KLA

Comment: As I read the regulation, certification application packets require copies of the facility's quality assurance plan, standard operating procedures and calculated quality control data per analysis/method pair. Just handling and preparing the paperwork will be overwhelming to most facilities. The referenced documents are revised as needed and as proposed must be reviewed annually. Therefore copies received and maintained by the state will be changed before the next recertification process. Additionally, why should fees be paid annually, applications be completed every other year and inspections should be expected every five years? I think there should be something more consistent.

(b) Response: The Cabinet believes that the documentation required to be submitted with the initial application should be readily accessible for the wastewater laboratory to copy because this documentation is required by current federal regulations. The Cabinet amended the regulation for renewal applications from every year to every two years based upon comments received from the stakeholder group. An identification of any changes to the QAP and SOPs is the only documentation required to be submitted with the renewal application. At the request of several stakeholders, the Cabinet provided in the regulation that a certified lab could pay fees annually, even though certification is for a two-year period.

(103) Subject Matter: Proficiency testing

(a) Commenter: Robin Strader, Leitchfield Wastewater Treatment Plant and KLA

Comment: Operator doing field analysis only will be required to do annual unknowns. Facilities only collecting samples may not have the class A volumetric glassware to or the pipetting to mix concentrates for analysis. Again submitting the data to PT providers can be cumbersome.

(b) Response: Other than requiring certification of wastewater laboratories, the proposed regulation, as amended, does not impose any additional requirements beyond the requirements of 40 CFR Part 136, which already apply to Clean Water Act §402 (NPDES) compliance data. The requirement to conduct annual PTs is in 40 CFR Part 136.

(104) Subject Matter: Wastewater versus drinking water PTs

(a) Commenter: Robin Strader, Leitchfield Wastewater Treatment Plant and KLA

Comment: Certified drinking water laboratories will not be allowed to use water studies samples in lieu of wastewater unknowns. As long as the analyte and method pair is acceptable for water and wastewater, there should not be another set of samples and the associated cost levied on the laboratory. Drinking water unknown ranges are usually lower than wastewater unknowns as well.

(b) Response: Other than requiring certification of wastewater laboratories, the proposed regulation, as amended, does not impose any additional requirements beyond the requirements of 40 CFR Part 136, which already apply to Clean Water Act §402 (NPDES) compliance data. The requirement to conduct annual PTs is in 40 CFR Part 136 and is method specific.

(105) Subject Matter: Certification costs

(a) Commenter: Robin Strader, Leitchfield Wastewater Treatment Plant and KLA

Comment: I am sure that the Commonwealth will lose many small labs in water and wastewater treatment plants because many managers, commissions and councils will not want to deal with another certification, another fee, etc. When these plants sub contract out compliance monitoring, those managers, commissions and councils see that as "lab cost". When instruments need to be upgraded or replaced or reagents need to be ordered, funding will not be there because the view will be "We send our lab work out. You don't need lab equipment and supplies." Therefore in the end, true harm could come to the waters of Kentucky because operators might not have access to instruments for process control and anyone who has ever been around a treatment plant knows you cannot make treatment decisions on two to three week old data supplied by a contract laboratory.

(b) Response: KRS 224.10-670 requires the Cabinet to establish a "certification program for laboratories that submit environmental data as it relates to analyses and laboratory tests for activities subject to 33 U.S.C. sec. 1342, includes standards for the operation of laboratories, fees for certification and competency evaluations, and the issuance of certificates of competency. Based upon investigations the Cabinet has conducted of laboratories in Kentucky conducting wastewater monitoring and testing services, the Cabinet has determined that quality control and quality assurance procedures at some wastewater laboratories are inadequate, in part, due to a lack of clear regulatory standards and certification programs for wastewater laboratories. The intent of the wastewater laboratory certification program is to ensure that the integrity of KPDES compliance data can be ascertained. The Cabinet has, as much as possible, taken every effort to minimize the cost and regulatory burden of the wastewater laboratory certification program. Other than requiring certification of wastewater laboratories, the proposed administrative regulation, as amended, does not impose any additional requirements beyond the requirements of 40 CFR Part 136, which already apply to Clean Water Act §402 (NPDES) compliance data.

(106) Subject Matter: Request for checklists and for audits

(a) Commenter: Robin Strader, Leitchfield Wastewater Treatment Plant and KLA

Comment: Plants-labs should have access to all information, checklist, etc. they will be inspected for during an audit. It would make preparation for and conducting the audit much neater and timely.

(b) Response: The Cabinet will conduct audits for compliance with the requirements in this proposed administrative regulation, as amended. All records that are subject to release under the Kentucky Open Records Act may be requested in writing to the Division of Water.

(107) Subject Matter: Commercial laboratory costs

(a) Commenter: Robin Strader, Leitchfield Wastewater Treatment Plant and KLA

Comment: The small systems in Kentucky have already had hard laboratory/monitoring budget hits with weekly vs. monthly monitoring and more recently the addition of phosphorus and total nitrogen monitoring. Systems like mine have made alliances with neighboring systems to reduce lab expenses. Under this regulation, my 2 MGD facility will be viewed as a commercial lab doing 3 sets of samples a week.

(b) Response: The Cabinet has, as much as possible, taken every effort to minimize the cost and regulatory burden of the wastewater laboratory certification program. the operational costs associated with compliance with the WLCP other than those costs realized

with certification fees, should not be new costs, but actual costs already realized by the requirement to comply with 40 CFR 136. In consideration of the smaller municipal wastewater laboratories, the Cabinet included tiering of fees, but recognizes that the federal requirements do not change based upon the size of the wastewater laboratory.

(108) Subject Matter: Commercial lab vs. wastewater facility

(a) Commenter: Robin Strader, Leitchfield Wastewater Treatment Plant and KLA

Comment: I applaud the staff involved in drafting this regulation. I think this regulation is geared toward a commercial laboratory and I feel it is excessive for water and wastewater facilities with trained, certified operators.

(b) Response: KRS 224.10-670 requires the Cabinet to establish a "certification program for laboratories that submit environmental data as it relates to analyses and laboratory tests for activities subject to 33 U.S.C. sec. 1342, includes standards for the operation of laboratories, fees for certification and competency evaluations, and the issuance of certificates of competency. Based upon investigations the Cabinet has conducted of laboratories in Kentucky conducting wastewater monitoring and testing services, the Cabinet has determined that quality control and quality assurance procedures at some wastewater laboratories are inadequate, in part, due to a lack of clear regulatory standards and certification programs for wastewater laboratories. The intent of the wastewater laboratory certification program is to ensure that the integrity of KPDES compliance data can be ascertained. The Cabinet has, as much as possible, taken every effort to minimize the cost and regulatory burden of the wastewater laboratory certification program. The wastewater laboratory certification program is applicable to all labs conducting KPDES compliance data analysis; the authorizing statute does not exempt analysis of compliance data conducted by certified water or wastewater operators from the requirements of the statute or authorized regulation.

(109) Subject Matter: KFTC supports the regulation

(a) Commenter: Suzanne Tallichet, KFTC

Comment: KFTC was one of the citizen groups that worked to uncover and correct the widespread abuse of discharge monitoring by the coal industry in Kentucky that lead to the discovery of the many incompetent laboratories the industry was using. KFTC supports the Cabinet's efforts to create a waste-water laboratory certification program.

(b) Response: The Cabinet acknowledges this comment.

(110) Subject Matter: Stakeholder group
(a) Commenter: Suzanne Tallichet, KFTC
Comment: We are also keenly aware of the systemic failures of the Cabinet in the recent past to effectively execute its mandatory duties of monitoring and enforcement in regard to its delegated KPDES program. We find it unacceptable that a "stakeholders working group" with members only representing the regulated industries and their friends was created and worked behind closed doors to draft this program. Since citizens bear the brunt of the pollution released into Kentucky's environment it is beyond our understanding why the Cabinet, while it professes to balance regulating pollution with protecting the environment and citizens, would not include representatives of citizen organizations in this working group.
(b) Response: The Cabinet has met the requirement of KRS 13A in promulgating this proposed administrative regulation, as amended.

(111) Subject Matter: Demonstration of capability requirements
(a) Commenter: Suzanne Tallichet, KFTC
Comment: In Sec. 7.1 Demonstration Of Capability (DOC) of the manual, it calls for an initial Demonstration of Capability (IDC): one analyst/tech shall successfully analyze 4 midrange concentration lab blanks. This is not adequate. The Cabinet should require all analyst/techs pass an appropriate competency examination before then successfully analyzing 4 blanks chosen from among all parameters, analytes, matrixes and technologies that the analyst/tech will be analyzing.
(b) Response: The Cabinet believes that the requirements for DOC are adequate to ensure the integrity of compliance data. Chapter III Section 7.1.1 of the Manual states that "an IDC shall be performed initially by each analyst." Initially each analyst must successfully complete an IDC before he or she is permitted to generate data that is intended to be submitted to demonstrate compliance. An Ongoing Demonstration of Capability (ODC) shall be done annually by the primary analyst and every five years for the backup analysts.

(112) Subject Matter: Demonstration of capability requirements
(a) Commenter: Suzanne Tallichet, KFTC
Comment: Under Demonstrations of Capability in the manual, it says, "once a year one analyst/tech will perform the test on 4 blanks and once per 5 year cycle all other backup analysts/techs will have to demonstrate." This is not adequate. For annual Demonstrations of Capability all analyst/techs that are doing analyzing should be required to demonstrate their capability by successfully analyzing 4 blanks chosen from all parameters, analytes, matrixes and technologies they analyze.

(b) Response: The Cabinet believes that the requirements for DOC are adequate to ensure the integrity of compliance data. Chapter III Section 7.1.1 of the Manual states that "an IDC shall be performed initially by each analyst." Initially each analyst must successfully complete an IDC before he or she is permitted to generate data that is intended to be submitted to demonstrate compliance. An Ongoing Demonstration of Capability (ODC) shall be done annually by the primary analyst and every five years for the backup analysts.

(113) Subject Matter: Chain of custody corrective actions

(a) Commenter: Suzanne Tallichet, KFTC

Comment: Section 4.1 Upon finding errors and anomalies in Chain-Of-Custody a corrective action plan must be created that is only reported to the client. These are very serious errors and should also be reported with a corrective action plan immediately to DOW for approval, monitoring and possible investigation.

(b) Response: The COC corrective action plans will be reviewed during on-site audits and the Cabinet will provide additional scrutiny of the COC corrective action process, as appropriate. Otherwise, the Cabinet believes that the certification process itself along with periodic on-site audits is sufficient to address this issue.

(114) Subject Matter: PT failure

(a) Commenters: Suzanne Tallichet, KFTC; Tim Joice, KWA

Comment: We believe the language regarding the use of proficiency tests, and subsequent revocation of certification needs to be strengthened. First, according to 401 KAR 5:320 § 7;9 proficiency tests must be submitted "at least annually by the primary analyst or technician." Then, in the Wastewater Laboratory Certification Manual, under Chapter II. General Laboratory Requirements, Section 5.5, the language suggests that if a proficiency test does not fall within the acceptance limits, then a "re-analysis of a separate PT sample shall be conducted until meeting PT acceptance limits within the same calendar year." Under 5.5.1 the language says, "If a certified laboratory receives two (2) consecutive unacceptable results for a PT Study for one or more contaminants, the laboratory shall submit a corrective action plan to DOW." With this logic, a laboratory could have an unacceptable PT study result in January, but be within the proposed regulatory structure to then do another PT Study in December, with unacceptable results, and only then be required to develop a corrective action plan. This is insufficient, and allows for a whole year to go by without sufficient corrective action. An investigation should begin immediately upon the first unacceptable result and require a second PT submitted within 60 days of an unacceptable result. Additionally, if a second study is unacceptable, the laboratory should be put under provisional status.

(b) Response: The Cabinet has amended Section 11(2)(b) of the proposed administrative regulation to state: "…If the wastewater laboratory fails a proficiency test study, the wastewater laboratory shall, within ninety (90) days after receiving notice of the failed proficiency test study, analyze a second proficiency test study with the results within the acceptance limits specified by an approved proficiency test study provider…". The Cabinet has also revised the Manual to add Section 5.5.2 to Chapter II that will require performing a successful second PT Study for the analyte/method pairing within 90 days of receipt of notice of failing a PT Study for that analyte/ method pairing.

(115) Subject Matter: PT requirements

(a) Commenter: Suzanne Tallichet, KFTC

Comment: Section 7.0 Requirements for Maintenance of Certification 7.1 says annually you must satisfactorily analyze "a PT sample." Does this mean one sample for one parameter? If so it is not adequate. All analyst/techs that are doing analyzing should be required to demonstrate their capability by successfully analyzing 4 blanks chosen from all parameters, analytes, matrixes and technologies they analyze.

(b) Response: The proposed administrative regulation, as amended, by incorporating the requirements of 40 CFR 136, requires that a certified wastewater laboratory shall satisfactorily analyze a PT sample for each method-analyte pair for which it is certified annually. The proposed annual/every five year demonstrations by the primary/secondary analysts is consistent with other certification programs. The EPA's DMR-QA program does not require secondary analysts to do PT studies; it requires only the wastewater laboratory to pass. The WLPC program requires the primary analyst to do the annual PT study so that the majority of actual sample analyses are performed by the person who recently demonstrated competence via the PT study. The intent of the wastewater laboratory certification program is to ensure that the integrity of KPDES compliance data can be ascertained. The Cabinet believes that the treatment of required PT studies strikes an appropriate balance between assurance of data integrity and costs of the program.

(116) Subject Matter: Cabinet's evaluation procedures

(a) Commenter: Suzanne Tallichet, KFTC

Comment: 7.3 says for on-site evaluations Kentucky "may do a combination of any of the following: On site Evaluation, PT sample results, Quality Control Results, Compliance Reports, Review of Requested Documentation." No intervals for these inspections are mentioned. On-site evaluations of all certified labs should be done

annually. The evaluations should include all of the following: PT sample results, Quality Control Results, Compliance Reports, Review of Requested Documentation.

(b) Response: The Cabinet believes that the design of the program will adequately monitor the wastewater laboratories and ensure the integrity of the data submitted to demonstrate compliance with KPDES permit requirements.

(117) Subject Matter: Certification downgrade procedures

(a) Commenter: Suzanne Tallichet, KFTC

Comment: Subsection (5) of Section 10 of the proposed regulation states "A wastewater laboratory with provisional certification may continue to analyze a sample for compliance purposes, but shall notify its client of the wastewater laboratory's provisional certification status prior to conducting an analysis for that client and shall provide that information in writing to the client." This section needs to state that a wastewater laboratory with provisional certification shall not analyze samples for compliance of any method-analyte for which it has been found to be deficient.

(b) Response: Provisional certification status is provided for a certified laboratory to address deficiencies identified in an audit or by proficiency test. If the Cabinet determines that a wastewater laboratory has not corrected the deficiency within three months, the Cabinet may begin the process of certification revocation established in Section 13 (3) of the proposed regulation.

(118) Subject Matter: Certification revocation procedures

(a) Commenter: Suzanne Tallichet, KFTC

Comment: Section 11 of the proposed regulation states the following:
"(1) The cabinet *shall* immediately revoke a wastewater laboratory's certification for any of the following reasons:
(a) Failure to use an analytical method established in 40 C.F.R. 136 or in the applicable permit;
(b) Reporting proficiency test study data from another laboratory as its own data;
(c) Engaging in falsification of data or another deceptive practice;
(d) Endangering public health or the environment through an operation associated with the wastewater laboratory;
(e) Refusal to allow or participate in an on-site audit conducted by the cabinet; or
(f) Persistent failure to report accurate compliance data to the cabinet.
(4) The wastewater laboratory may request, in writing, a redetermination of the cabinet's intent to revoke certification pursuant to subsection (3) of this section.

(a) If a redetermination is requested, the request shall be made within thirty (30) days of receipt of the notice of intent to revoke.
(b)1. This request shall be submitted to the cabinet and shall explain the basis for the redetermination request and, if appropriate, include a written corrective action plan to address the deficiency identified in the cabinet's notice of intent to revoke.
2. The request shall be signed by a responsible official of the wastewater laboratory."
Section (4) is unnecessary and burdensome on the cabinet. The cabinet should be in ongoing communication with the laboratory concerning correction of the deficiency/corrective action plan during the 3 months of provisional certification before it decides to issue notice of intent to revoke certification.

(b) Response: The Cabinet notes that in what is identified as a reiteration of the proposed administrative regulation, as amended, the commenter inserted the word "shall" in place of "may," essentially removing the Cabinet's discretion with regards to revoking a wastewater laboratory's certification to a mandatory action if any of the reasons listed in Section 13 (1) of the proposed administrative regulation, as amended, has occurred. The Cabinet believes that the level of discretion afforded in this regulation is appropriate.

Regarding the burden and lack of necessity for the process allowing for a request for redetermination of the Cabinet's intent to revoke certification pursuant to Section 13 of the proposed regulation, the Cabinet believes that the process afforded the wastewater laboratory in Section 13 (4) of the proposed administrative regulation, as amended, is appropriate.

(119) Subject Matter: Cabinet's evaluation procedures

(a) Commenter: Suzanne Tallichet, KFTC

Comment: Subsection (5) of Section 11 "The cabinet, having received a request for redetermination pursuant to subsection (4) of this section, shall make a final determination whether or not to continue provisional certification, approve certification, or revoke certification, and shall provide written notice to the wastewater laboratory of this action." There is no time limit on how long the cabinet has to make the final determination. 30 days is reasonable.

(b) Response: The Cabinet believes that because the facts and circumstances of each of these situations vary considerably it would be unnecessary and inappropriate to prescribe a timeline to resolve or take final action to resolving certification issues. Therefore the Cabinet has not made a change to the proposed administrative regulation, as amended, in response to this comment.

(120) Subject Matter: Certification revocation procedures

(a) Commenter: Suzanne Tallichet, KFTC

Comment: Subsection (3) of Section 11 "If a wastewater laboratory has not corrected the deficiency resulting in the provisional certification status within three (3) months of written notification from the cabinet of the change to provisional certification, the cabinet shall provide written notice to the wastewater laboratory of the cabinet's intent to revoke the waste water laboratory's certification for any method-analyte pairing involved in the deficiency." This should not be a revocation just for a particular method-analyte the certification of the entire laboratory should be noticed with intent to revoke. This is burdensome to the Cabinet and allows a laboratory to be operated that is substandard.

(b) Response: The Cabinet believes that its approach to provisional certification on a method-analyte pairing basis is appropriate. The comment provides no basis for its conclusion other than the presumptive burden on the Cabinet. The proposed administrative regulation, as amended, requires the certified laboratory with provisional certification to notify its clients of the provisional certification status prior to conducting an analysis, and requires the laboratory to correct the deficiency as soon as reasonable possible, not to exceed three months of the certification status change. Therefore the Cabinet has not made a change to the proposed administrative regulation, as amended, in response to this comment.

(121) Subject Matter: KWA supports the regulation

(a) Commenter: Tim Joice, KWA

Comment: This program is a welcome addition to the Kentucky Division of Water's efforts to have better control and oversight over discharge monitoring reports submitted by permitted facilities and projects. As DOW is aware, there have been several concerning instances of malpractice between permit holder and wastewater laboratories over the years. Presumably, this will help reduce such issues. As noted in the document detailing 401 KAR 5:320, DOW is not required by 40 C.F.R. Part 136 to develop and implement a wastewater laboratory certification program. In development of the program, however, DOW is required to meet the analytical methods and instrumentation required in 40 C.F.R. Part 136. Upon review of the public-noticed materials, KWA is primarily in support of the program and DOW's efforts.

(b) Response: The Cabinet acknowledges the comment.

(122) Subject Matter: Certification period

(a) Commenter: Tim Joice, KWA

Comment: Under the proposed 401 KAR 5:320 § 4, the "Term of Certification Periods" is outlined. KWA is especially supportive of an annual certification, which must be renewed each year to maintain the certification. Iowa DNR utilizes a two-year cycle for their program, and in our view, that is too much time. The annual cycle reduces the possibility of extended periods that open the possibility for errors in equipment and employee negligence. However, we understand the additional workload of such a requirement. The current language of the proposed regulation suggests a one-year certification for the first year of the program's existence, and then a two-year certification beginning January 1, 2015 available to all applicants, existing and new. KWA suggests that for all new laboratory facilities that apply for certification, regardless of the time of application, they each be required to undergo an initial one-year certification period, followed by a two-year certification. This ultimately provides an evaluation year, and helps verify, before provided a full two-year certification, that the facility is operating according to the proposed regulations and 40 C.F.R. Part 136.

(b) Response: Based on concerns raised by stakeholders, the Cabinet has amended the proposed administrative regulation regarding the effective date(s) of the proposed administrative regulation. The effective date of the proposed administrative regulation, as amended, is January 1, 2014, for general wastewater laboratories. The effective date of the proposed administrative regulation, as amended, is January 1, 2015 for Field Only Wastewater Laboratories. All wastewater laboratories certifications will be effective for a period of two years. The Cabinet believes that the frequency of certification is adequate to ensure integrity of compliance data and is a more manageable approach for certified laboratories and the Cabinet.

(123) Subject Matter: KWA support for fee structure

(a) Commenter: Tim Joice, KWA

Comment: KWA generally supports the fee structure established, and appreciates that DOW intends for the program to be self-sufficient, such that personnel funding will be provided via the fees paid by applicants.

(b) Response: The Cabinet acknowledges the comment.

(124) Subject Matter: KWA support for incorporation by reference

(a) Commenter: Tim Joice, KWA

Comment: KWA supports the additional documents that are incorporated into the regulation, including the Wastewater Laboratory Certification Manual, EPA's *Methods for Measuring the Acute Toxicity of Effluents and Receiving Waters to Freshwater and Marine Organisms* and EPA's *Short-term Methods for Estimating the*

Chronic Toxicity of Effluents and Receiving Waters to Freshwater Organisms.

(b) Response: The Cabinet acknowledges the comment.

(125) Subject Matter: KWA support for auditing authority

(a) Commenter: Tim Joice, KWA

Comment: KWA strongly supports 401 KAR 5:320 § 8, which establishes auditing authority for the cabinet. This ensures accountability for the wastewater laboratory. We also appreciate and support the language regarding provisional certification and subsequent revocation of a certification.

(b) Response: The Cabinet acknowledges the comment.

(126) Subject Matter: Proficiency tests and revocation of certification

(a) Commenter: Tim Joice, KWA

Comment: With regard to provisional status, and eventual revocation of certification, KWA suggests that a laboratory with provisional certification for specific method-analyte pairing(s) be disallowed from analyzing samples for compliance of that (or those) specific pairings. It certainly contradicts the purpose of the program if facilities are continued to operate under a "business as normal" environment, even though they have been found to have issues with their operations, equipment, and/or employees.

(b) Response: Provisional certification status is provided for a certified laboratory to address deficiencies identified in an audit or by proficiency test. If the Cabinet determines that a wastewater laboratory has not corrected the deficiency within three months, the Cabinet may begin the process of certification revocation established in Section 13 (3) of the proposed regulation. The Cabinet believes that its approach to provisional certification on a method-analyte pairing basis is appropriate. The comment provides no basis for its conclusion other than the presumptive burden on the Cabinet. The proposed administrative regulation, as amended, requires the certified laboratory with provisional certification to notify its clients of the provisional certification status prior to conducting an analysis, and requires the laboratory to correct the deficiency as soon as reasonable possible, not to exceed three months of the certification status change. Therefore the Cabinet has not made a change to the proposed administrative regulation, as amended, in response to this comment.

(127) Subject Matter: Proficiency tests and revocation of certification

(a) Commenter: Tim Joice, KWA

Comment: 401 KAR 5:320 § 11 states "the cabinet may immediately revoke a wastewater laboratory's certification for any of the following

reasons." We suggest modifying to language to be "the cabinet *shall* immediately revoke," leaving no room for debate.

(b) Response: The Cabinet believes using the word "shall" in place of "may," essentially removes the Cabinet's discretion with regards to revoking a wastewater laboratory's certification to a mandatory action if any of the reasons listed in Section 13 (1) of the proposed administrative regulation, as amended, has occurred. The Cabinet believes that the level of discretion afforded in this regulation is appropriate.

(128) Subject Matter: Field analysis

(a) Commenter: Bill Bissett, KCA

Comment: KCA strongly supported the enactment of House Bill 385 by the 2011 Kentucky General Assembly (codified as KRS 224.10-670) authorizing the wastewater laboratory certification program and participated actively in the workgroup established to develop implementing regulations. Accordingly KCA generally supports promulgation of the proposed regulation. Nevertheless KCA urges the Division of Water to give careful consideration to the comments of affected entities to avoid unnecessary regulatory burdens. During the development of the proposed regulation KCA has consistently urged the Division of Water to limit the scope of the regulation to those functions traditionally understood to constitute laboratory work rather than related activities such as monitoring and sample collection. In general the proposed regulation has been limited to traditional laboratory activities; however, 401 KAR 5:320, as proposed, still addresses some activities that do not constitute "laboratory" work including the following which appear in the Wastewater Laboratory Certification manual incorporated by reference as a part of the regulation:
Section 4.1 addresses "in-stream monitoring";
Section 5.1.2 addresses sample collection for WET testing;
Section 5.1.3 addresses receiving streams sampling.
KCA recommends that these provisions be deleted since they are not within the scope of KRS 224.10-670.

(b) Response The Cabinet appreciates KCA's support for the WLCP and appreciate the comments. The Cabinet has, as much as possible, taken every effort to minimize the cost and regulatory burden of the program. Other than requiring certification of wastewater laboratories, the proposed regulation, as amended, does not impose any additional requirements beyond the requirements of 40 CFR Part 136, which already apply to Clean Water Act §402 (NPDES) compliance data. However, the Cabinet believes that field analyses should be viewed and treated differently than the more complex analyses conducted in a laboratory. In that regard, the Cabinet has proposed to simplify the certification process for "Field Only"

wastewater laboratories. The cabinet is developing SOP and QAP templates to assist facilities in obtaining "Field Analysis Only" certification. A KPDES permitted facility that is providing field analyses for its own facility is exempt from certification fees in accordance with this regulation. It is also important to note that process-control analyses are not subject to this regulation.

The requirements in the Manual apply only to laboratories certified pursuant to this administrative regulation. The Cabinet appreciates the concern and is revising Chapter II Section 4.1 of the Manual to remove the requirements that address field sampling. Sample collection must be conducted in compliance with the facility's KPDES permit, required QAP and the applicable requirements in the methods identified in 40 CFR Part 136. The notable exception to this being field analysis. If the person collecting KPDES compliance samples is also conducting field analyses as defined in the proposed administrative regulation, that person must be associated with a wastewater laboratory certified for Field Analysis

The Cabinet agrees that the Wastewater Laboratory Certification Manual should not provide guidance for or include requirements not in 40 CFR 136 in regards to WET testing. Therefore, the Cabinet is revising Chapter V of the Manual to revise the introduction (1.1) and remove Sections 1.2 and 1.3.

(129) Subject Matter: Lab personnel requirements
(a) Commenter: Fanto Bayo, City of Frankfort
Comment: The regulation should make it clear whether operators and part-time lab personnel need to participate in the Demonstration of Capabilities, method detection limits and Proficiency Testing.
(b) Response: Chapter III Section 7.1.1 of the Manual states that "an IDC shall be performed initially by each analyst." Initially each analyst must successfully complete an IDC before he or she is permitted to perform an analysis from which are intended to be submitted for compliance purposes. An ongoing Demonstration of Capability (ODC) shall be done annually by the primary analyst and every five years for the backup analysts. Chapter III Section 7.1 of the Manual requires a method detection limit study (MDL) annually. Section11 (2)(b) of the proposed administrative regulation, as amended, requires that the primary analyst perform and pass a PT Study annually.

(130) Subject Matter: Economic impact of certification program
(a) Commenter: Chad Harpole, Kentucky Chamber of Commerce
Comment: The Cabinet appears to underestimate the economic impacts of the proposed program. Section 2 indicates that, as of 1 July 2014, all

environmental data from analyses or tests subject to 33 U.S.C 1342 (the NPDES program, implemented in Kentucky through KPDES permits) must arise from analysis or testing performed by a Cabinet-certified "wastewater laboratory". Section 1 defines a "wastewater laboratory" as a lab that performs an analysis or test subject to 33 U.S.C 1342, falling within nine "analysis categories" (including "field analysis"). The implication of this broad definition is that any facility performing a KPDES test or analysis is a "wastewater laboratory" and subject to lab certification program requirements. Given that the certification program incorporates common KPDES parameters for which the data is almost certainly developed by the facility itself (e.g., flow, temperature, pH, and other field tests that don't require an actual on-site laboratory), the universe of facilities to be classified as "wastewater laboratories" is likely to include the entire population of facilities holding KPDES permits, as well as any contract labs they may use for KPDES compliance. The Cabinet's regulatory impact analysis indicates that the program will apply to: 97 municipal labs; 16 industrial labs; 110 commercial labs; and 59 field service labs. The Cabinet does not explain how it arrived at these figures or define the categories of applicable facilities. However, it seems doubtful that the Cabinet has included, within its estimate for applicable facilities, all KPDES permit holders that perform at least one analysis or test. Likewise, it seems unlikely the Cabinet has accounted for all contract laboratories, whether located inside or outside Kentucky, which provide at least occasional analytical services or permit support for KPDES facilities. As proposed, all of these entities will need to register, pay fees, and be audited and certified by the Cabinet.

The proposed lab certification program will increase the compliance burdens and costs for KPDES facilities through several mechanisms. In addition to annual fees, some facilities that currently perform simple measurements or tests to comply with their permits will resort to hiring contract labs so as to minimize compliance burdens arising from the new program. Predictably, there will be a reduction in the pool of available contract labs as labs located outside Kentucky, otherwise providing competent services, weigh the additional costs of doing business in Kentucky and leave the market. Though KRS 224.10-670 authorizes the Cabinet to promulgate regulations establishing this wastewater laboratory certification program, the statute is short on specifics and affords the Cabinet broad discretion in setting program requirements. The excessive impacts from the proposed regulation can be avoided by minimizing requirements that apply to tests not performed in a true wastewater lab, or not subject to an approved analytical method, as follows.

(b) Response: The Cabinet has, as much as possible, made every effort to minimize the cost and regulatory burden of the program. Other than requiring certification of wastewater laboratories, the proposed regulation, as amended, does not impose any additional requirements beyond the requirements of 40 CFR Part 136, which already apply to Clean Water Act §402 (NPDES) compliance data. However, the Cabinet believes that field analyses should be viewed and treated differently than the more complex analyses conducted in a laboratory. In that regard, the Cabinet has proposed to simplify the certification process for "Field Only" wastewater laboratories. The cabinet is developing SOP and QAP templates to assist facilities in obtaining "Field Analysis Only" certification. A KPDES permitted facility that is providing field analyses for its own facility is exempt from certification fees in accordance with this regulation. It is also important to note that process-control analyses are not subject to this regulation.

(131) Subject Matter: Record retention policy

(a) Commenter: Chad Harpole, Kentucky Chamber of Commerce

Comment: The Certification Manual incorporated by reference into the proposed regulation requires certified laboratories to maintain records for five years or until the next on-site audit, whichever is longer. Consistent with federal recordkeeping requirements under the NPDES permit program as set forth at 40 CFR 122.41(j) and 401 KAR 5:065 Section 2, this requirement should be revised to provide that except for records relating to a KPDES permittee's sewage sludge use and disposal activities, which shall be retained for a period of at least five years (or longer as required by 40 CFR part 503), records shall be maintained for a period of 3 years from the date of the sample, measurement, report or application.

(b) Response: The Cabinet believes that inn performing an on-site audit, the Cabinet must be able to review all data relevant to determining compliance since the last on-site audit. The WLCP must require records to be maintained for five years or until the next on-site audit, whichever is longer. The Cabinet notes that 401 KAR 5:065 applies to KPDES permittees while the WLCP applies to wastewater laboratories.

(132) Subject Matter: Support for certification program

(a) Commenter: Eric Chance, Appalachian Voices

Comment: Appalachian Voices would like to commend the cabinet for proposing this certification program. Appalachian Voices was one of several organizations party to the lawsuits against several coal companies for false wastewater monitoring data that spurred the passage of KRS 224.10-670, and the subsequent development of these rules. The problem of falsely reporting wastewater data was

widespread within the coal industry, and within the labs that serviced it. We greatly appreciate the cabinet's efforts including this rule, to address these problems. Accurate self-reporting is the backbone of the Clean Water Act. Without accurate data state and federal laws put in place to protect the people, streams and wildlife of Kentucky become meaningless and unenforceable. We believe that ensuring that accurate data is being submitted to state and federal agencies is a vital first step in the in the protection of the state's natural resources and so we applaud the cabinet for acting on the power given to it under KRS 224.10-670 to begin the process of promulgating standards for wastewater labs in the state. While implementing standards on wastewater laboratories is a vital step in ensuring that labs submit accurate data there are several easily correctable deficiencies that undermine the effectiveness of this proposed rule. We believe that with some corrections, this proposed certification program will go a long way towards ensuring accurate reporting of wastewater data in the coal industry and will allow for effective implementation of other existing environmental laws. We appreciate the cabinet's efforts to correct the serious problems at many of the laboratories in Kentucky.

(b) Response: The Cabinet acknowledges the comment.

(133) Subject Matter: Discretionary duties given to the Cabinet should be mandatory

(a) Commenter: Eric Chance, Appalachian Voices

Comment: Under the current proposed rule, many of the responsibilities given to the cabinet such as document reviews and on site audits are discretionary rather than mandatory. We strongly urge the cabinet to make such duties mandatory in order to provide the public and the regulated community the assurance that the regulations are being meaningfully implemented. I'm sure members of the regulated community would like assurance that they are not spending additional money on fees and tests and submitting additional paperwork only to have their certification given the rubber stamp of approval without thorough review and audits by the agency. If these standards are truly being put forth to help ensure that the coal industry accurately report their water monitoring data rather than simply to shield them from future liability for false reporting then the cabinet should assure everyone that it will perform all the duties currently proposed. In part this regulation came about because cabinet personnel were not performing their duties and thoroughly reviewing the waste water data being submitted by coal companies. Had someone at the cabinet been reviewing the Discharge Monitoring Reports submitted by Frasure Creek, International Coal Group and Nally & Hamilton Enterprises, enforcement actions should have been taken far before we discovered the blatant false reporting that lead to our

lawsuits and eventually spurred the proposal of this certification program. We urge you to not repeat these mistakes. Without further assurances that the cabinet will fulfill those duties which are currently discretionary under this rule it has the potential of becoming the worst of both worlds. A regulation that is both costly and burdensome to those it regulates while providing the general public none of the protections they deserve. The discretionary duties that should be mandatory include:
Section 8(1) of the regulation, should require DOW to perform annual unannounced onsite audits.
Section 9 (2)(a) of the regulation, should require DOW to both review requested documents and complete an onsite audit.
Section 11(1)(a-f), of the regulation, should require the cabinet to revoke certification for any of the reasons listed in section 11(1)(b-f). All of the causes of action in section 11 are serious problems and should result in the revocation of certification, with the exception of Section 11(1)(a) (failure to use acceptable analytical methods), which depending on the severity of the violation may constitute ground for certification revocation.
Section II 7.3 of the manual, should require rather than allow DOW to consider all of the information (on site evaluations, PT sample results, QC results, compliance reports and requested documents) available to verify that a laboratory is meeting the required standards.

(b) Response: The Cabinet does not respond to specific allegations made by the commenter that are beyond the scope of the content of this proposed administrative regulation, as amended. The Cabinet believes the requirements of the proposed administrative regulation, as amended, will ensure confidence in the compliance data submitted in accordance with 33 USC 1342, and the level of discretion afforded in this regulation is necessary and appropriate.

(134) Subject Matter: Audits and inter-lab comparisons

(a) Commenter: Eric Chance, Appalachian Voices

Comment: In the current draft manual section II 3.10 requires that each laboratory include its audit and inter-laboratory comparisons in its Standard Operating Procedures (SOP), but there is no further requirement for a schedule of these. In order to demonstrate ongoing proficiency, the manual should include requirements that audits and inter-laboratory comparisons be completed quarterly in order to meet A2LA standards.

(b) Response: The Cabinet considered the requirements of various laboratory standards in developing the WLCP and believes that its approach is appropriate. The Cabinet does not believe that the inter-laboratory comparison adds additional benefits that are not already gained through the PT Study requirements.

(135) Subject Matter: Field sampling

(a) Commenter: Eric Chance, Appalachian Voices

Comment: The administrative rule and manual should clearly require that any entity (including KPDES permittees) doing field sample collection or field analysis to be reported for KPDES compliance purposes, should be required to either be certified or meet all the applicable standards set out in this regulation and its associated materials. Additionally, it is vital that field sampling records clearly indicate which methods are used (single grab or flow or time based composites), as well sample preservation, volume and representativeness in the chain of custody and/or field notes. This point concerns sections II 4, III 5.6, V 1.2.7 and V 1.3.7 of the Manual.

(b) Response: Other than requiring certification of wastewater laboratories, the proposed regulation, as amended, does not impose any additional requirements beyond the requirements of 40 CFR Part 136, which already apply to Clean Water Act §402 (NPDES) compliance data. However, the Cabinet believes that field analyses should be viewed and treated differently than the more complex analyses conducted in a laboratory. In that regard, the Cabinet has proposed to simplify the certification process for "Field Only" wastewater laboratories. The cabinet is developing SOP and QAP templates to assist facilities in obtaining "Field Analysis Only" certification. A KPDES permitted facility that is providing field analyses for its own facility is exempt from certification fees in accordance with this regulation. It is also important to note that process-control analyses are not subject to this regulation.

(136) Subject Matter: Standards for personnel

(a) Commenter: Eric Chance, Appalachian Voices

Comment: Section II 1 should specify minimum requirements for education and experience of laboratory staff. For example, at minimum supervisory staff should have a bachelor's degree in a science-based field, and a specified minimum number of credits in chemistry.

(b) Response: The proposed administrative regulation is intended to certify the laboratories and not establish a certification program for the individuals doing a laboratory analysis. The Cabinet notes that the applicable federal requirements likewise do not establish minimum requirements for education or experience of laboratory staff. However, Chapter II Section 1.0 of the Manual does require that the laboratory has "sufficient supervisory, quality assurance and technical staff with the necessary education, training, technical knowledge, and experience for their assigned functions."

(137) Subject Matter: Standards for personnel

(a) Commenter: Eric Chance, Appalachian Voices

Comment: Each lab should have a QA/QC person who is trained and independent of daily lab operations. This person should report to the laboratory owner and not the laboratory manager, in order to ensure effective oversight. This person should have oversight and access to all QA/QC, data validation and reporting to clients and agencies.

(b) Response: The proposed administrative regulation is intended to certify the laboratories and not establish a certification program for the individuals doing a laboratory analysis. The Cabinet notes that the applicable federal requirements likewise do not establish minimum requirements for education or experience of laboratory staff. However, Chapter II Section 1.0 of the Manual does require that the laboratory has "sufficient supervisory, quality assurance and technical staff with the necessary education, training, technical knowledge, and experience for their assigned functions."

(138) Subject Matter: Standards for personnel

(a) Commenter: Eric Chance, Appalachian Voices

Comment: Training records required in section II 2 of the manual should include specific requirements including records that demonstrate proficiency for each analytical method being used. Training records should also specifically include all general lab procedures as well as specific methods performed.

(b) Response: The Cabinet agrees. Chapter II Section 2.0 of the Manual does require that the records maintained shall include "job-related formal education and training courses taken by the analyst/technician that pertain to his or her responsibilities, including analytical methodology, laboratory safety, sampling, quality assurance, data analysis, etc." The WLCP does require a demonstration of proficiency for each analyte-method pairing for which the wastewater laboratory is certified. In that the suggested training records are already required in the Manual, no change is necessary.

(139) Subject Matter: Standards for personnel

(a) Commenter: Eric Chance, Appalachian Voices

Comment: Training records should also be available for personnel who only complete field sampling. These records should include training on all analytical methods being used for field measurements, field sampling techniques being used as well as proper chain of custody procedures.

(b) Response: The Cabinet agrees; training records for personnel performing field analysis are required just as they are for personnel performing analyses for other analysis categories. Chapter II Section 2.0 of

the Manual does require that the records maintained shall include "job-related formal education and training courses taken by the analyst/technician that pertain to his or her responsibilities, including analytical methodology, laboratory safety, sampling, quality assurance, data analysis, etc." In that the suggested training records are already required in the Manual, no change is necessary.

(140) Subject Matter: Reporting and record keeping
(a) Commenter: Eric Chance, Appalachian Voices
Comment: Section II 6 of the manual should include requirements to periodically assess the integrity of all computational and reporting systems. Section II 6.2 should require precision and accuracy statements for each data set should be reported or available even if they are not required to be submitted for compliance purposes. Also, section 11 6.3 should require that enough raw data to reconstruct reported results must be retained and easily accessible.
(b) Response: Chapter II Section 6.7 of the Manual requires that all computer programs be verified initially and that they remain accessible to authorized personnel only. Chapter II Section 6.3 of the Manual requires that all records be maintained for five years or until the next on-site audit, whichever is longer. These records shall include all raw data, calculations, and quality control data. The Cabinet would be able to reconstruct reported results from the records retained with the requirements listed in Chapter II Section 6.3 of the Manual. In addition, precision and accuracy can be determined from these records. The Cabinet respectfully disagrees that requiring a separate statement to be prepared and filed for all compliance data is necessary to be able to ascertain compliance with the WLCP.

(141) Subject Matter: Alternative test methods
(a) Commenter: Eric Chance, Appalachian Voices
Comment: Sections III 1.1 any alternative test methods in addition to being approved by DOW, should also be required to be equivalent to approved test methods for performance standards such as minimum detection limit and precision and accuracy.
(b) Response: Any method approved for use via the Alternate Testing Procedures or Method Modification Procedures must meet the requirements of 40 CFR 136.4, 136.5 or 136.6. Authority to approve an alternative test method (ATP) is not delegated to the States; the EPA has sole authority to approve an ATP.

(142) Subject Matter: Traceability of standards
(a) Commenter: Eric Chance, Appalachian Voices

Comment: Section III 7.4 and section II 9 should clearly specify that all standards of any type are easily traceable.

(b) Response: The Cabinet agrees. Chapter II Section 8.8 of the Manual states that "calibrations of measurement devices shall be traceable to national standards, if applicable." This requirement in the General Laboratory Requirements chapter applies to all other chapters of the Manual.

(143) Subject Matter: In stream standards

(a) Commenter: Eric Chance, Appalachian Voices

Comment: Section VI of the manual "Critical Elements for In-Stream Monitoring" is currently reserved. We believe that this section in its entirety should be made available for public comment before the rule is approved.

(b) Response: The Cabinet has removed the reserved Chapter VI from the Manual. Any revisions made to the Manual after the proposed administrative regulation goes into effect are required to comply with the KRS 13A administrative regulatory process, including public notice, public comment, and opportunity for public hearing.

(144) Subject Matter: Definitions of MRL, RRL, and RLS

(a) Commenter: Judy Morgan, ESC Lab Sciences

Comment: Section 6.2.9 – Requires use of MRL on the reports. Throughout the document the following acronyms are being used for the same standard: RRL, MRL, RLS, ICCS, RLC. Many of these are not defined and some of the references do not exist. For example: ICCS on B.4 refers to the "Reporting Limit Check" (RLC) which is not in the definitions in Appendix B. We are uncertain of the reason why KY has chosen terms that are undefined and do not generally exist in known and current terminology used by established programs.

(b) Response: RRL is the Required Reporting Limit, which is established by the State or the EPA (usually in the permit). MRL is the Minimum Reporting Limit that a laboratory can achieve and is specific to an individual laboratory. The MRL is not the same as the RRL, but the MRL must be at least equal to, or less than, the RRL. The Reporting Limit Standard (RLS) is used to verify that the laboratory is capable of meeting its MRL. See Chapter III Section 7.1 in its entirety. The Cabinet agrees that ICCS and RLC are not used in the body of the Manual and will be deleted from its appendices.

(145) Subject Matter: Equivalency

(a) Commenter: Judy Morgan, ESC Lab Sciences; Alan Wood, AEP

Comment: Equivalency is not addressed in the manual.

(b) Response: Equivalency is addressed in Section 1(3) of the proposed administrative regulation, as amended, and in the application for certification: Kentucky Wastewater Laboratory Certification Program Application.

(146) Subject Matter: Demonstration of capability requirements
(a) Commenter: Judy Morgan, ESC Lab Sciences
Comment: In Section 7.1.1 IDC/ODC it states "each of the four IDCs (or ODCs) are within 80 to 120% of the mean value; and." We are curious where 80 – 120% originates? We assume that this is from the SDWA Program, but cannot find any NPDES requirements for this range. Some organic compounds will not meet this criteria.
(b) Response: Some analytical methods include an acceptable range to demonstrate a method's ability to reach the required reporting limits established in a KPDES permit. However, the EPA has not developed guidelines for methods for which an acceptable range has not been established. Where this range is not established, 80-120% is commonly accepted by the industry as meeting this requirement. The Cabinet believes that this 80-120% range is appropriate, but notes that Chapter III Section 7.1.1 of the Manual does allow for using other established criteria for a specific method.

(147) Subject Matter: Demonstration of capability requirements
(a) Commenter: Judy Morgan, ESC Lab Sciences
Comment: It is unclear how the options below are to be used:
the calculated percent relative standard deviation (%RSD) is at or below 15%; other limits may apply as specified in the method or individually approved by DOW based on method performance.
(b) Response: There are some methods that have recovery ranges that may be outside of the established acceptance criteria; those methods specify the recovery ranges within the method itself. In those instances, the requirements of the method should be met. For methods that do not have written requirements, the bulleted items from Chapter III Section 7.1.1 of the Manual shall be used. Other appropriate laboratory-derived acceptance criteria will be considered.

(148) Subject Matter: MDL study requirements
(a) Commenter: Judy Morgan, ESC Lab Sciences
Comment: In Section 7.1.2 MDL, the established replicates shall be analyzed over 2 – 3 non consecutive days." The section requires the use of 40 CFR Part 136 Appendix B. We cannot find a reference to this requirement in Appendix B or any other currently approved guidance document. This will cause a scheduling hardship for

many laboratories, thus we request that you reconsider this requirement as no other program currently requires this.

(b) Response: The Cabinet disagrees that this requirement should be modified. The intent of the MDL study process is to demonstrate variability in order to achieve a more realistically derived MRL. The Cabinet believes that it is appropriate to have these studies performed over 2-3 non-consecutive days in order to achieve this goal. The Cabinet agrees that 40 CFR Part 136 Appendix B does not address the issue of performing the analysis over consecutive days; this requirement in Chapter III Section 7.1.2 of the Manual is established to develop uniform procedures to be used by all certified wastewater laboratories. Performing the MDL study over 2-3 non-consecutive days provides for variability that is more representative of environmental samples, thereby resulting in a more realistic calculated MDL.

(149) Subject Matter: Equivalency for certification

(a) Commenter: Judy Morgan, ESC Lab Sciences; Alan Wood, AEP

Comment: Page 2 – Line 10 – Equivalency is vague. We are a NELAP, ISO 17025, & DOD accredited laboratory and are uncertain regarding whether any of these accreditations are suitable for equivalency. In addition, what does equivalency allow? Do we still submit PT results? Must we still be audited by KY? We are looking for clarification. Typical reciprocity between programs prevents duplication of effort by allowing recent audits and PT reviews to be performed by the reciprocal program. Is a copy of the laboratory's current Accreditation Certificate sufficient or does detailed laboratory documentation need to be submitted for review? AEP recommends the March 2013 Wastewater Laboratory Certification Manual includes information necessary for determining equivalency, and/or an approved list of equivalent state certification programs or organizations, such as from the National Environmental Laboratory Accreditation Conference (NELAC).

Although the Wastewater Laboratory Certification Manual includes an acronym and defines NELAC, there are no other references discussed in the manual. The Division of Water should consider including laboratories certified under NELAC as meeting the equivalency of certification criteria. Otherwise, the reference should be removed if no other information related to NELAC will be included in the Manual.

(b) Response: The proposed administrative regulation, as amended, recognizes other national accreditation standards and makes provisions for laboratories certified under other accreditations to seek certification in accordance with this regulation via the

"equivalency of certification" provision in Section 1(3) "Equivalency of certification," which means certification of a wastewater laboratory by an entity, other than the cabinet, whose requirements for certification are determined by the cabinet to meet the requirements of this administrative regulation.

Section 5 of the application titled Kentucky Wastewater Laboratory Certification Program Application for Kentucky Laboratory Certification provides an option for initial and renewal equivalency of certification, directing the applicant to complete Section 9 or 12, respectively. Sections 9 and 12 of the application provide the list of what information is required to be submitted for equivalency of certification. The additional information required for initial equivalency certification is: (a) Scope of work, which includes a copy of the current certificate and a list of analytes currently certified along with the reference method, instrument, laboratory minimum reporting limit, method detection limit, and units for each analyte, and (b) The most recent final audit report issued by the certifying authority, including any corrective action plan, and any other information required by the Cabinet to demonstrate compliance with all of the requirements for initial certification.

The Cabinet agrees with the suggestion regarding removing the references to NELAC in the Manual and has removed the abbreviation and definition of NELAC in the Appendices to the Manual.

(150) Subject Matter: Equivalency for certification
(a) Commenter: Judy Morgan, ESC Lab Sciences
Comment: In Section 9 "Initial Equivalency" 6. and 7. – Requirements for MDL and IDC – This is a lot of information to submit, especially a full service environmental lab participating in all programs and utilizing methods from EPA. Standard Methods, and EPA ORCR SW-846. Since most "equivalent" accreditors review these documents, will it be necessary to submit these documents to be approved.
(b) Response: The Cabinet believes that it is important to review these documents and other information to ensure that all requirements of the Cabinet's program are met by a wastewater laboratory accredited by another entity.

(151) Subject Matter: Demonstration of capability requirements
(a) Commenter: Judy Morgan, ESC Lab Sciences
Comment: It is also required that the laboratory submit MDLs and IDCs for every method requested. For most methods, we combine the QC

and adopt the tightest criteria. Will one MDL or IDC be accepted as long as all methods are listed?

(b) Response: Unless the different methods are performed in an identical manner, it is necessary to submit an MDL and an IDC for each method. If all method criteria are met with one analysis, then it would be acceptable to submit one MDL and one IDC for these methods.

(152) Subject Matter: Analytical method for total residual chlorine

(a) Commenter: Alan Wood, AEP

Comment: Total residual chlorine is listed as an approved field analysis under Section 1 of the proposed rule. However, Section 2(2)(a) of the rule specifies environmental data from analyses shall be performed in compliance with an analytical method in 40 CFR Part 136. Since AEP's preferred method for analysis of total residual chlorine due to site-specific interferences is Method 330.3, which is an EPA-approved method for monitoring total residual chlorine, AEP requests that the use of any EPA-approved method for monitoring a listed field parameter be acceptable under the regulation. The Division may also consider developing a more detailed definition for the term "field analysis", rather than just listing approved parameters.

(b) Response: The EPA lists approved methods in 40 CFR Part 136. EPA 330.3 is no longer an approved method for analyzing total residual chlorine; it was removed in the 2007 Method Update Rule (MUR). If an iodometric technique is needed, see SM 4500-Cl B (2000). The Cabinet notes that Section (3)(a)(1) of the proposed administrative regulation, as amended, allows a different analytical method to be used if that method is established in the applicable permit. Thus, if there is not an acceptable method listed in 40 CFR Part 136 and there is not an EPA-approved ATP for a specific circumstance, a different test method could be approved through the KPDES permit process, which undergoes review by the EPA.

(153) Subject Matter: Quality Assurance Plan – Instrument Calibration

(a) Commenter: Alan Wood, AEP

Comment: Section 3.6.4 of the Certification Manual specifies "*Use control charts for calibration check standards to monitor for trends and ensure acceptance criteria are met.*" This criterion is vague as it implies there should be control charts for all quality control. This is problematic for certain tests, for example in ICP metals analyses, where the laboratory typically charts laboratory reagent blanks and laboratory fortified blanks. There are also sample matrix spikes and several instrument quality control samples to verify the validity of the calibration curve, carryover, and interference compensation. None of these checks however are trended on control charts. Therefore, AEP requests Section 3.6.4 be revised to

"*Use control charts for designated control samples to monitor for trends and ensure acceptance criteria are met.*"

(b) Response: Maintaining control charts, or other trend analyses of quality control results, is a requirement of 40 CFR 136.7. The Cabinet has added the phrase "or other trend analyses of quality control results" to Chapter II Section 3.6.4 of the Manual to allow for trend analyses other than control charts to be used.

(154) Subject Matter: Quality Assurance Plan – Type and Frequency of Quality Control Checks

(a) Commenter: Alan Wood, AEP

Comment: Section 9.1.12 of the Certification Manual identifies "*Parameters for chemistry and radiochemistry shall include or reference qualitative identification/confirmation of contaminants*." AEP requests this section is clarified to note what identification or contamination is being referenced (e.g., laboratory reagent blank).

(b) Response: Chapter II Section 3.9.1.12 of the Manual requires a list of the individual analytes for the QC of any group contaminant. The laboratory is to identify which analytes they are using for confirmation when the applicable methods do not require all target analytes in the QC.

(155) Subject Matter: Audit Costs

(a) Commenter: Alan Wood, AEP

Comment: Section 8(4)(a) of the draft rule identifies *If an on-site audit of a wastewater laboratory located outside of Kentucky is conducted by the cabinet, the wastewater laboratory shall bear the cost of the audit.* AEP would be affected by this provision as the Dolan Technology Laboratory is located in Ohio and provides periodic analyses for wastewater samples collected in Kentucky. The regulation should not simply state "the laboratory shall bear the cost of the audit" as expenses incurred could be excessive and unwarranted. Alternatively, the regulations should reference 200 KAR 2:006, which outline reimbursable travel expenses for state employees.

(b) Response: The Cabinet acknowledges the concern expressed by this comment. The Cabinet has amended the proposed administrative regulation to state "…the wastewater laboratory shall bear the reasonable cost of the audit."

(156) Subject Matter: Application of the regulation

(a) Commenter: Annette DuPont-Ewing, KMUA

Comment: This program regretfully is modeled after the Drinking Water Laboratory Certification program. This is wastewater and most of the testing is done as water leaves the treatment plant. The original legislation was a result of mismanagement in the coal industry.

KMUA and its members agreed that if the Division of Water was willing to work with us on building this regulation then we wouldn't testify against the bill, -but here we are this evening.

(b) Response: The Cabinet believes the WLCP meets the current federal requirements relating to wastewater laboratory analyses, including 40 CFR Part 136.

(157) Subject Matter: Uncertainty in enforcement

(a) Commenter: Annette DuPont-Ewing, KMUA

Comment: City owned utilities are dedicated stewards of clean water and other protection of water quality and the human health. City owned utilities have skilled and certified wastewater laboratory technicians that are doing a great job every day and have been for decades with no complaints. However, we find ourselves in this situation of uncertainty. We have heard DOW employees provide direction on how the regulation is to be enforced at the KWWOA meeting but none of that is written in specifics and with certainty. What happens if someone new to the program decides to interpret things differently? There are too many unknowns and too much room for interpretation in enforcement. Reasonableness in enforcement continues to be a concern. We've seen the results of this type of uncertainty – as has the Division of Water – when the EPA issues a new regulation. We can't have folks making up enforcement as they go along.

(b) Response: Based upon investigations the Cabinet has conducted of laboratories in Kentucky conducting wastewater monitoring and testing services, the Cabinet has determined that quality control and quality assurance procedures at some wastewater laboratories are inadequate, in part, due to a lack of clear regulatory standards and certification programs for wastewater laboratories. Due to these findings, the Cabinet proposed and the Kentucky General Assembly adopted legislation during the 2011 regular session to create standards and a certification program for laboratories conducting analysis of wastewater for KPDES program purposes. The legislation was codified at KRS 224.10-670, which became effective June 8, 2011. This proposed administrative regulation, as amended, establishes the wastewater laboratory certification program, standards for the certification of wastewater laboratories, and fees for certification and evaluation of wastewater laboratories. The intent of the wastewater laboratory certification program is to ensure that the integrity of KPDES compliance data can be ascertained. The Cabinet has, as much as possible, taken every effort to minimize the cost and regulatory burden of the wastewater laboratory certification program. The Cabinet will determine via document reviews and on-site audits whether compliance with federal requirements and the Cabinet's regulation are being met.

401 KAR 5:320 establishes the progressive enforcement process, including addressing deficiencies through to certification revocation process.

(158) Subject Matter: Unintended consequences

(a) Commenter: Annette DuPont-Ewing, KMUA

Comment: Given the new costs of complying with this regulation, many municipal utilities are seriously considering outsourcing all the wastewater laboratory work. If a big utility like Bowling Green Municipal Utilities is weighing the benefits of pushing out its work to a commercial laboratory – what chance does the smaller laboratories like Berea, Glasgow and Frankfort have? Perhaps this is the intent of the regulation? Perhaps this reflects a push to force all city-owned utilities to commercial laboratories? Having the big commercial laboratories at the table may have been an example of their undue influence in the process. Their comments to the Division of Water certainly do not reflect any consideration for municipal utility laboratories. And neither does the regulation.

Another unintended consequence is the potential cut back on extra sampling. Instead of sampling BOD 5 times a week, most municipal labs will now do only the minimum to save costs. The new costs of sending this sample out to commercial labs will be cost prohibitive for a sample that is tested 5 days after it leaves the system. Does a five day old sample protect the water quality at any level – NO.

(b) Response: The intent of the Cabinet in developing the WLCP is to ensure the integrity of the data being submitted to the Cabinet for KPDES permit compliance purposes. The stakeholder group was selected so that representatives of all types of wastewater laboratories would be available to comment on the WLCP. This included representatives of small municipal wastewater laboratories as well as representatives of large commercial wastewater laboratories. In consideration of the smaller municipal wastewater laboratories, the Cabinet included tiering when appropriate, but recognized that the federal requirements do not change based upon the size of the wastewater laboratory.

The Cabinet has, as much as possible, taken every effort to minimize the cost and regulatory burden of the program. Other than requiring certification of wastewater laboratories, the proposed regulation, as amended, does not impose any additional requirements beyond the requirements of 40 CFR Part 136, which already apply to Clean Water Act §402 (NPDES) compliance data.

(159) Subject Matter: SOP review timeframe

(a) Commenter: Michael Campbell, Marathon
Comment: NELAC certification requires a review of SOPs once every three years as opposed to the proposed WLCP requirement for annual SOP reviews. The WLCP requirement should match the NELAC requirement.
(b) Response: The Cabinet believes the annual SOP review is appropriate to ensure the integrity of compliance data required by USC 1342. A "review" of the SOPs should not be onerous, but is intended as a normal practice to ensure the SOPs align with current methods and procedures being used in the certified laboratory.

(160) Subject Matter: Analytical test modifications
(a) Commenter: Michael Campbell, Marathon
Comment: Analytical test modifications should be approved only by the EPA.
(b) Response: The authority to approve analytical test modifications, as opposed to approving an Alternative Test Procedure, may be delegated to the States, and EPA Region 4 has delegated that authority to the Cabinet. The Cabinet, in approving a test modification, first must make a determination that the test modification complies with the requirements of 40 CFR 136.6, and second, collaborates with EPA Region 4 staff to ensure that the EPA staff concur that the test modification is approvable.

IV. Summary of Action Taken by Promulgating Agency

The Energy and Environment Cabinet reviewed the comments and, as a result, is amending the administrative regulation as follows:

Page 2
Section 1(4)(e)
Line 18

After "Conductivity;", insert "and".

Page 2
Section 1(4)(f)
Line 19

After "Turbidity", delete "; and".

Page 2
Section 1(4)(g)
Line 20

Delete "(g) Flow.".

Page 2
Section 1
Line 20

Insert the following:

"(5) "Field-only wastewater laboratory" means a wastewater laboratory that performs a measurement for only the parameters identified as field analysis. The measurement may take place outdoors, in an on-site room used as a laboratory, or in an off-site laboratory.

(6) "General wastewater laboratory" means a wastewater laboratory that performs an analysis for at least one analysis category other than field analysis, although the general wastewater laboratory may also perform a field analysis measurement."

Page 2
Section 1(5)
Line 21

Before "Interim certification", insert "(7)".

Delete "(5)".

Page 2
Section 1(5)
Line 23

Before "of this administrative regulation.", insert "10".

Delete "8".

Page 3
Section 1(5)
Line 1

After "until the cabinet has completed an", insert "on-site".

Page 3
Section 1(6)
Line 2

Before "Primary analyst or technician", insert "(8)".
Delete "(6)".

Page 3
Section 1(7)
Line 5

Before "Wastewater laboratory", insert "(9)".
Delete "(7)".

Page 3
Section 2
Line 7

After "Section 2.", insert the following:

Effective Date for this Administrative Regulation. The effective date for this administrative regulation shall be:
(1) January 1, 2015, for general wastewater laboratories; and
(2) January 1, 2016, for field-only wastewater laboratories.
Section 3.

Page 3
Section 2
Line 7

After "Requirement for Acceptance of Environmental Data.", insert "(1)".

Page 3
Section 2
Line 8

After "KRS 224.10-670(2)", insert "and the schedule in subsection (2) of this section".
Delete "beginning July 1, 2014,".

Page 3
Section 2
Line 9

After "tests submitted", insert "to the cabinet".

Page 3

Section 2
Line 9

After “33 U.S.C. 1342”, delete “,”.

Page 3
Section 2
Line 10

Before “By a certified wastewater laboratory; and”, insert “(a)”.
Delete “(1)”.

Page 3
Section 2
Line 11

Before “In compliance with:”, insert “(b)”.
Delete “(2)”.

Page 3
Section 2
Line 12

Before “An analytical method”, insert “1.”.
Delete “(a)”.

Page 3
Section 2
Line 12

After “An analytical method in 40 C.F.R.”, insert “Part”.

Page 3
Section 2
Line 13

Before “This administrative regulation;”, insert “2.”.
Delete “(b)”.

Page 3
Section 2
Line 14

Before The provisions of the Commonwealth”, insert “3.”.
Delete “(c)”.

Page 3
Section 2
Line 16

Before “Section 3.”, insert the following:

“(2) The requirements in subsection (1) of this section shall begin on:
(a) January 1, 2015, for a general wastewater laboratory; and

(b) January 1, 2016, for a field-only wastewater laboratory."

Page 3
Section 3
Line 16

After "Section", insert "4".
Delete "3".

Page 3
Section 3
Line 16

After "Certification Requirements. The", insert the following:
"requirements established in this section shall".
Delete "following requirements".

Page 3
Section 3
Line 21

After "applicable fee as established in Section", insert "8".
Delete "6".

Page 4
Section 4
Line 8

After "Section", insert "5".
Delete "4".

Page 4
Section 4
Line 8

After "Term of Certification Periods", insert "for a General Wastewater Laboratory".

Page 4
Section 4(1)
Line 8

After "(1) The", insert "initial".
Delete "first".

Page 4
Section 4(1)
Line 8

After "certification period", insert "for a general wastewater laboratory shall be".
Delete "is".

Page 4
Section 4(1)
Line 8

After “certification period is from”, insert “January 1, 2014,”.
Delete “July 1,”.

Page 4
Section 4(1)
Line 9

Before “until December 31”, delete “2013,”.

Page 4
Section 4(1)
Line 9

After “December 31,”, insert “2015”.
Delete “2014”.

Page 4
Section 4(1)
Line 10

After “January 1,”, insert “2016”.
Delete “2015”.

Page 4
Section 4(2)
Line 11

After “If, beginning January 1,”, insert “2016”.
Delete “2015”.

Page 4
Section 4(2)
Line 11

After “If, beginning January 1, 2015, a”, insert “general”.

Page 4
Section 4(2)
Line 12

After “for a new method-analyte pairing, the”, insert “initial”.

Page 4
Section 5
Line 15

After “Section”, insert “7”.
Delete “5”.

Page 4
Section 5

Line 15

Before "Section 5", insert the following:

Section 6. Term of Certification Periods for a Field-Only Wastewater Laboratory. (1) The initial certification period for a field-only wastewater laboratory shall be from January 1, 2015, until December 31, 2016, and subsequent certification periods shall be consecutive two (2) year periods, beginning January 1, 2017.

(2) If, beginning January 1, 2017, a field-only wastewater laboratory applies for initial certification of the wastewater laboratory or for certification for a new method-analyte pairing, the initial certification period shall be the two (2) year period as established in subsection (1) of this section, based upon the date of application receipt by the cabinet.

Page 4
Section 5(1)
Line 18

After "November 15 of the", insert "odd-numbered".
Delete "even-numbered".

Page 4
Section 5(1)
Line 18

After "of the current certification period", insert the following:
"for a general wastewater laboratory, or November 15 of the even-numbered year of the current certification period for a field-only wastewater laboratory".

Page 4
Section 5(2)
Line 23

After "December 15 of the", insert "odd-numbered".
Delete "even-numbered".

Page 5
Section 5(2)
Line 1

After "year of current certification period", insert the following:
"for a general wastewater laboratory, or after November 15 but on or before December 15 of the even-numbered year of the current certification period for a field-only wastewater laboratory".

Page 5
Section 5(2)
Line 2

After "established in Section", insert "8".

Delete “6”.

Page 5
Section 5(3)
Line 7

After “December 15 of the”, insert “odd-numbered”.
Delete “even-numbered”.

Page 5
Section 5(3)
Line 8

After “certification period”, insert the following:
“for a general wastewater laboratory, or after December 15 of the even-numbered year of the current certification period for a field-only wastewater laboratory”.

Page 5
Section 5(3)
Line 9

After “established in Section”, insert “8”.
Delete “6”.

Page 5
Section 5(3)
Line 10

After “December 31 of that”, insert “odd-numbered”.
Delete “even-numbered”.

Page 5
Section 5(3)
Line 10

After “of that even-numbered year”, insert the following:
“for a general wastewater laboratory, or after December 31 of that even-numbered year for a field-only wastewater laboratory,”

Page 5
Section 6
Line 12

After “Section”, insert “8”.
Delete “6”.

Page 5
Section 6(2)
Line 18

After “audit pursuant to Section”, insert “10”.
Delete “8”.

Page 6
Section 6(3)
Line 1

After "The applicable certification fee", insert "shall be".
Delete "is".

Page 6
Section 6(3)
Line 1

After "by November 15 of each year. In", insert "odd-numbered".
Delete "even-numbered".

Page 6
Section 6(3)
Line 2

After "years of the certification period", insert the following:
"for a general wastewater laboratory, or in even-numbered years of the certification period for a field-only wastewater laboratory".

Page 6
Section 6(5)(b)
Line 17

Before "(3) of this administrative regulation.", insert "7".
Delete "5".`

Page 8
Section 7
Line 1

After "Section", insert "9".
Delete "7".

Page 8
Section 7(1)(c)
Line 8

After "established in 40 C.F.R.", insert "Part".

Page 8
Section 8
Line 16

After "Section", insert "10".
Delete "8".

Page 8

Section 8(1)
Line 17

After “during normal business hours”, delete “without prior”.

Page 8
Section 8(1)
Line 18

Delete “notification”.

Page 9
Section 8(4)(a)
Line 1

After “the wastewater laboratory shall bear the”, insert “reasonable”.

Page 9
Section 9
Line 3

After “Section”, insert “11”.
Delete “9”.

Page 9
Section 9
Line 13

After “American Association for Laboratory Accreditation”, insert the following:

“. If the wastewater laboratory fails a proficiency test study, the wastewater laboratory shall, within ninety (90) days after receiving notice of the failed proficiency test study, analyze a second proficiency test study with the results within the acceptance limits specified by an approved proficiency test study provider”.

Page 9
Section 10
Line 21

After “Section”, insert “12”.
Delete “10”.

Page 9
Section 10(1)
Line 23

After “Section”, insert “11”.
Delete “9”.

Page 10

Section 10(2)
Line 6

After "meet the requirements of Section", insert "11".
Delete "9".

Page 11
Section 11
Line 3

After "Section", insert "13".
Delete "11".

Page 11
Section 11(1)(a)
Line 3

After "Failure to use an analytical method established in 40 C.F.R.", insert "Part".

Page 12
Section 12
Line 14

After "Section", insert "15".
Delete "12".

Page 12
Section 12
Line 14

Before "Section 12", insert the following:

"Section 14. Cabinet to Develop Templates. (1) The Cabinet shall develop templates to assist wastewater laboratories in preparing a quality assurance plan (QAP) and standard operating procedures (SOPs) applicable for field analysis measurements.

(2) The templates developed by the Cabinet shall address all applicable requirements for a QAP and common device SOPs, but will require the inclusion of site-specific information to be provided by the wastewater laboratory.

(3) The cabinet shall provide public notice and at least a thirty (30) day opportunity for public review and comment on the proposed templates before finalizing these templates.

(4) These templates may be used by a field-only wastewater laboratory or for the field analysis portion by a general wastewater laboratory. A wastewater laboratory is not required to use these templates, and may independently develop its own QAP and SOPs.

(5) The Cabinet shall make the final templates available on its web site."

Page 12
Section 12(a)
Line 16

After ""Commonwealth of Kentucky Wastewater Laboratory Certification Manual","

insert “June”.
Delete “March”.